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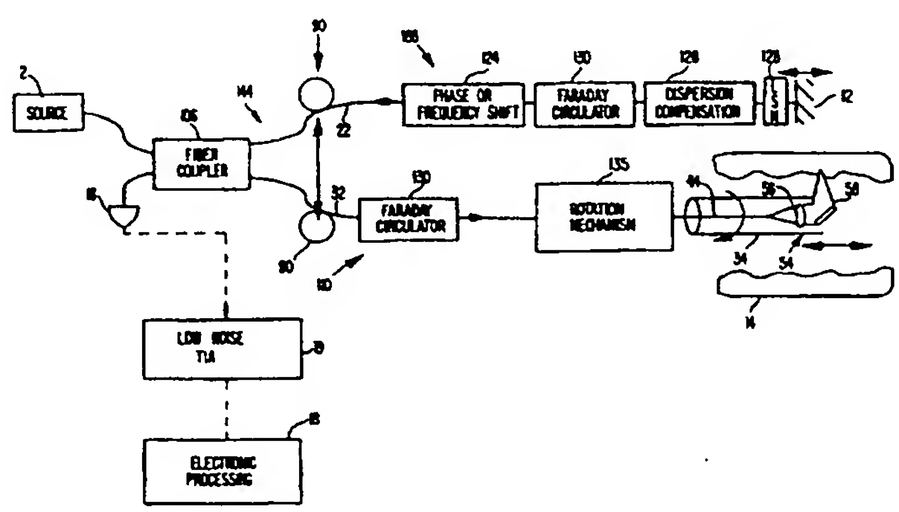
(54) Title: METHOD AND APPARATUS FOR PERFORMING OPTICAL MEASUREMENTS USING A FIBER OPTIC IMAGING GUIDEWIRE, CATHETER OR ENDOSCOPE



(57) Abstract

An imaging system for performing optical coherence tomography includes an optical radiation source; a reference optical reflector; a first optical path leading to the reference optical reflector; and a second optical path coupled to an endoscopic unit. The endoscopic unit preferably includes an elongated housing defining a bore; a rotatable single mode optical fiber having a proximal end and a distal end positioned within and extending the length of the bore of the elongated housing; and an optical system coupled to the distal end of the rotatable single mode optical fiber, positioned to transmit the optical radiation from the single mode optical fiber to the structure and to transmit reflected optical radiation from the structure to the single mode optical fiber. The system further includes a beam divider dividing the optical radiation from the optical radiation source along the first optical path to the reflector and along the second optical path; and a detector positioned to receive reflected optical radiation from the reflector transmitted along the first optical path and reflected optical radiation transmitted from the structure along the second optical path. The detector generates a signal in response to the reflected optical radiation from the reference reflector and the reflected optical radiation from the structure, and a processor generating an image of the structure in response to the signal from the detector. The system provides both rotational and longitudinal scanning of an image.

Method and Apparatus for Performing Optical Measurements using a Fiber Optic Imaging Guidewire, Catheter or Endoscope

Cross-Reference to a Related Application

This application is a continuation in part of U.S. Serial No. 08/492,738, filed on June 21, 1995, pending; and is a continuation in part of 08/577,366, filed on December 22, 1995, pending; and is a continuation in part of U.S. Serial No. 08/252,940, filed on June 2, 1994, pending, which is a continuation in part of 08/033,194, filed on March 16, 1993, now U.S. Patent No. 5,459,570, which is a continuation of 07/692,877, filed on April 29, 1991, now abandoned, the contents of which are all incorporated herein by reference.

Field of Invention

This invention relates to the field of optical imaging and more specifically to the field of medical imaging with interferometric detection.

Background of the Invention

Over the past decade there have been tremendous advances in biomedical imaging technology. For example, magnetic resonance imaging, X-ray computed tomography, ultrasound, and confocal microscopy are all in widespread research and clinical use, and have resulted in fundamental and dramatic improvements in health care. However, there are many situations where existing biomedical diagnostics are not adequate. This is particularly true where high resolution (~ 1 μm) imaging is required. Resolution at this level often requires biopsy and histopathologic examination. While such examinations are among the most powerful medical diagnostic techniques, they are invasive and can be time consuming and costly. Furthermore, in many situations conventional excisional biopsy is not possible. Coronary artery disease, a leading cause of morbidity and mortality, is one important example of a disease where conventional diagnostic excisional biopsy can not be performed. There are many other examples where biopsy can not be performed or conventional imaging techniques lack the sensitivity and resolution for definitive diagnosis.

Moreover, for medical procedures such as balloon angioplasty, conventional techniques have not been able to provide high resolution imaging of the artery while a balloon is being inflated. Many other interventional procedures would greatly benefit from high resolution, in-

housing for delivering fluid to the structure in question. The endoscopic unit can further include one or more inflatable balloons for performing procedures such as balloon angioplasty, for maintaining the opening in a vessel.

The interferometer of the system further includes a beam divider which divides the optical radiation from the optical radiation source along the first optical path to the reflector and along the second optical path to the structure being viewed. The optical radiation detector is positioned to receive reflected optical radiation from the reflector and reflected optical radiation from the structure and to generate a signal in response to the reflected optical radiation. A processor utilizes the signals from the detector to generate an image of the structure being viewed.

In one embodiment the reference optical reflector is typically coupled to a movable actuator to provide periodic movement to the reference mirror. In another embodiment the movable reference mirror is replaced with a static reference mirror and the broadband optical source replaced with a narrow bandwidth frequency tunable source, such as a semiconductor laser with tunable external gratings, a tunable solid state laser, or a dye laser. With such a source, optical radiation reflected from the structure being observed will arrive at the detector after the radiation reflected from the reference mirror is received at the detector. If the source is frequency modulated this delay will result in a beat frequency that is dependent on the difference between the distance from the detector to the reflection site within the structure, and the distance from the detector to the reference reflector. In still other embodiments of the present invention, the detector forming part of the imaging system includes a polarization diversity receiver, or alternatively a polarization analyzer. In still another embodiment the source consists of a broad band optical source, an interferometric detector using an optical spectrum analyzer wherein the Fourier transform of the spectrum is used to derive the reflectance profile of the sample.

It should be noted, that as used herein, the term endoscopic, applies to medical as well as non-medical imaging. One example of non-medical imaging in which the present invention may be used is as a replacement for a borescope to detect faults in cavities and bores in various industrial applications. For purposes of discussion only, the description to follow describes the present invention in terms of medical imaging, but the it is not the intent to limit the applications so described herein. Furthermore although the term endoscope is used, this invention directly relates to guidewires, catheters, and imaging with probes placed through trocars.

Fig. 15 depicts an embodiment of an interferometer of the present invention including a polarization diversity receiver.

Fig. 16 depicts an embodiment of the imaging system of the present invention, utilizing wave division multiplexing.

Fig. 17 depicts a non-longitudinal scanning embodiment of the imaging system of the present invention, utilizing a narrow bandwidth, frequency tunable optical source.

Fig. 18 depicts a non-longitudinal scanning embodiment of the imaging system of the present invention, utilizing a Fourier transform spectroscopy.

Fig. 19 depicts an alternate embodiment of the invention whereby the imaging system of the present invention is integrated with a laser surgical device.

By rotating the optical radiation beam emitted from the endoscopic unit 34, rotational scanning may be accomplished. In rotational scanning, a circumferential path whose radius is centered at the longitudinal axis of the endoscopic unit 34 is viewed.

OPTICAL SOURCES

Considering each component in more detail, the optical source 2 has characteristics such as wavelength, power, coherence length, and autocorrelation function which are important factors in system performance. In some applications, near infrared sources (1.0 - 2.0 um) tend to penetrate deeper into many biological media than visible wavelengths and are therefore preferable. The optical radiation source 2 can include in various embodiments: semiconductor sources (light emitting diodes (LED), edge emitting diodes (ELED), superluminscent diodes (SLD), mode-lock lasers (e.g. $TiAl_2O_3$, $Cr:Mg_2SiO_4$, $CrLiSrAlF_6$), rare earth doped fibers (REDF) (Yb, Nd, Er, Pr, Tm), and super-continuum or Raman sources. For REDF in order to obtain a good coherence length and autocorrelation function, it may be necessary to insert short period Bragg gratings or long period Bragg gratings into the fiber or use filters external to the fiber to shape the Amplified Spontaneous Emission spectrum (ASE). LED and ELED devices are very-low cost broad bandwidth devices having coherence lengths less than 10 μm. Their main limitation is that typically they have very low power (< 100 μW) when coupled into a single spatial mode. SLDs typically have a short coherence length of about ~ 10 μm, and power of about ~ 2 mW. Actively and passively mode-locked lasers offer very high power (> 100 mW) and short coherence length (< 5 μm). Additionally, source powers in excess of 100 mW and coherence lengths under 10 μm can be used. Spectrally shaped REDF, particularly cladding pumped fibers offer good performance in many applications.

INTERFEROMETERS

Referring to Fig.'s 2A and 2B, there are several varieties of interferometers that may be used in the system of the present invention. Although bulk optical and free space implementations are shown in these figures, there exist equivalent embodiments employing optical fibers. One embodiment employs a simple Michelson Interferometer 104, as shown in Fig. 2A. In another embodiment, as shown in Fig. 2B, the interferometer 204 includes a sample reference reflector 213 in the measuring arm 210. The use of this reference reflector 213 in the measuring arm 210 allows for long displacements between beamsplitter 211 and sample 214.

LONGITUDINAL SCANNING MECHANISMS

Referring to Fig. 4, the methods for performing longitudinal scanning are addressed. In order to maintain good detection sensitivity in rotational priority scanning the reference light must be frequency shifted to move the interference signal away from baseband 1/f-type noise and to prevent aliasing using serrodyne techniques with a phase shifter or an acousto-optic frequency shifter 124. In this figure, either a longitudinal scanning mechanism 128 can be used to move the reference reflector 12, or a fiber stretcher 90 can be used to change the path length. The longitudinal scanning mechanism 128 can include for example, a stepper motor, a DC servo-motor, or an electromagnetic speaker coil. The length or extent of movement by the longitudinal scanning mechanism 128 is preferably at least slightly greater than the desired scanned depth range in the structure. The longitudinal scanning mechanism 128 preferably has a velocity at which it moves the reference reflector 12 that is uniform at least during the times when scanning occurs, i.e. a step function. Alternatively the velocity imparted by the longitudinal scanning mechanism 128 may take the form of a ramp or sawtooth function. A movement detector (not shown) can further be coupled to the longitudinal scanning mechanism 128 to detect the position of the reference reflector 12 in order to achieve uniform motion of the reference reflector 12 or to sense the actual velocity profile and correct for the nonuniform velocity in electronic processing unit 18. More specifically, the longitudinal scanning mechanism 128 can be coupled to a uniform motion system (not shown), capable of transmitting a signal indicative of desired position of the reference reflector 12 at each point in the travel path of the reference reflector 12 to be compared against a signal from a position detector (not shown). Any resulting error signal is then utilized to control the longitudinal scanning mechanism 128 to maintain the reference reflector 12 moving at a desired constant velocity.

As shown in the embodiments of Fig.'s 4 and 5A, modulation can be carried out with fast fiber stretching using two piezoelectric transducers (PZT) comprising a piezoelectric modulator-type spool around which the optical fibers are wound. As shown in this figure, both the optical fiber 22 of the reference arm 188 and the optical fiber 32 of the measuring arm 110 can thus be wound around a PZT or around another suitable form that can be expanded or contracted using actuation. Each PZT may be driven out of phase, so that as the PZTs periodically stretch the fibers 22, 32 to change the lengths of the optical paths of the reference 188 and measurement 110

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shown) at its distal end 47. Within the bore 43 of the housing 42 resides an optical fiber 44, which is, in one embodiment a flexible single mode optical fiber or a single mode fiberoptic bundle having standard, or polarizing maintaining, or polarizing fibers to insure good polarization mode matching. The optical fiber 44 is preferably encased in a hollow flexible shaft 46. As the endoscopic unit 34 both illuminates and collects retroreflected light the optical fiber 44 is preferably a single mode optical fiber. The use of a single mode fiber is preferable for applications of OCT imaging because it will propagate and collect a single transverse spatial mode optical beam which can be focused to its minimum spot size (the diffraction limit) for a desired application. Preferably the single mode optical fiber 44 consists of a core, a cladding, and a jacket (not shown). The radiation beam is typically guided within the glass core of the fiber 44 which is typically 5 - 9 microns in diameter. The core of the fiber is typically surrounded by a glass cladding (not shown) in order to both facilitate light guiding as well as to add mechanical strength to the fiber 44. The cladding of the fiber is typically 125 microns in diameter.

An irrigation port 62 is formed near the distal end 47 of the housing 42 for irrigating the structure being imaged. The rotational scanning mechanism 35 causes rotation of the optical fiber 44 or a component of an optical system 54 disposed at the distal end 47 of the optical fiber 44. The housing 42 includes a transparent window 60 formed in the area of the distal end 47 and adjacent the optical system 54 for transmitting optical radiation to the structure 14 being imaged. The rotational scanning mechanism 35 enables the optical radiation to be disposed in a circular scan. When combined with longitudinal scanning, as described above, the imaging depth of the optical radiation is changed, as further described below.

Referring to Fig. 7A, the optical radiation beam can be emitted out of the distal end of the endoscopic unit 34 or out of the side of the endoscopic unit 34 at an angle, ϕ, to the axis of the endoscopic unit 34. The beam emission direction is scanned rotationally by varying its angle of emission, θ, along the axis of the endoscopic unit 34. The optical radiation beam can further be directed at an angle, ϕ, which deviates from 90 degrees. This facilitates imaging slightly ahead of the distal end of the endoscopic unit 34. In this implementation, the emitted beam scans a pattern which is conical. with a conical angle of 2ϕ. When used with longitudinal scanning, this scan pattern generates a cross sectional image corresponding to a conical section through the artery or vessel or tissue, as further shown in Fig 14. The angle ϕ may be adjustable, as to cam be responsive to control signals from signal processing and control electronics 18 or manually adjustable. Due to the adjustability of the angle, nearly all forward imaging, mainly transverse

replaced with each patient. In addition to these means of coupling, additional modifications for high-speed optical imaging are possible. Either standard or gradient index (GRIN) lenses (not shown) can be used to couple light from the fixed to rotating portion of the catheter. Because more optical elements are involved, alignment of all components to the high tolerances (< 1 mrad angular tolerance) are required for adequate coupling.

The optical connector 48 functions as the drive shaft for the endoscopic unit 34, as the rotation mechanism is coupled thereto. The rotation mechanism includes a DC or AC drive motor 74 and a gear mechanism 76 having predetermined gear ratios. The gear mechanism 76 is coupled to the motor 74 via a shaft 78. In all embodiments, upon activation of the drive motor 74, the shaft 78 rotates causing the gear mechanism 76 and the rotatable optical fiber 44 or a component of the optical system 54 to rotate. Alternatively, the DC drive motor 74 can be a micromotor (not shown) disposed at the distal end of housing, connected to optical system 54 causing rotation or translation of a component of the optical system 54 as further described in Fig. 10.

In embodiments where a fiber is not rotated but a component of the optical system is rotated via a flexible coupling mechanism alternative drive mechanisms to those shown in Fig. 6 and Fig. 8 are possible. Among these drive mechanisms are an "in-line" drive analogous to a drill wherein shaft 78 directly links "in line" with flexible shaft 46. A stationary sheath is used outside shaft 46 to protect fibers which are routed between the sheath and the housing 42.

The optical system 54 can include a number of different optical components depending on the type of scan desired. Referring again to the embodiment of Fig. 6, the optical system 54 includes a lens 56 and an optical beam director 58. The beam director 58 may include a lens, prism, or mirror constructed so as to minimize the effects of turbulence on the beam propagation. In this embodiment, the beam director 58 is preferably a mirror or prism affixed to a GRIN lens 56 for directing optical radiation perpendicularly to the axis of the endoscopic unit 34. The housing 42 includes a transparent window 60 formed along the wall of the endoscopic unit 34. In this embodiment the scan of Fig. 7C is achieved, as the optical radiation is directed perpendicularly through the transparent window 60 and onto the structure 14 of interest.

Referring to Fig. 6, in this embodiment, it is seen that by removing ultrasound components 61 and beam director prism or mirror element, high resolution imaging is possible if the endoscopic unit 34 has a window 160 at the tip of the endoscopic unit 34. In this embodiment the optical system includes a beam director which is a lens 156, which transmits light in a circular path

ribbed sleeve (not shown) or grooves (not shown) in sheath 1180. Although the sheath 1180 is tightly torsionally coupled, it is allowed to slide axially and is driven by linear motor 1181 with suitable coupling means to two plates 1182 affixed to the sheath 1180. Thus, as the motor 1174 drives torque cable 1146 in rotation, the linear motor 1181 can drive the sheath 1180 axially. At the distal end of the endoscopic unit is a mirror beam directing optic 1158. This mirror is hinged in two ways. One hinge 1176 is connected to torque cable 1146 in a torsionally stiff way to drive the mirror in rotation. Another single hinge point 1177 is connected to sheath 1180 so as to drive the mirror in tip and tilt in response to motor 1181. Housing 1142 is suitably metered off of sheath 1180 so as to protect mirror 1177 from contacting the outer the housing 1142. In another embodiment sheath 1180 is directly affixed to torque cable 1146 and the mirror 1158 is replaced with prism beam director attached directly to lens 1156. Gearing mechanism is suitably made to allow motor 1181 to axially drive the entire endoscopic imaging unit in the axial direction. These example embodiments enable beam 1199 to perform automated three dimensional maps of the sample of interest.

Another alternative embodiment of the endoscopic unit 34 of the present invention is shown in Fig. 10. In this embodiment, the optical system 54 preferably comprises a lens 256, a retroreflector such as a prism 59, and a beam director 158 such as a mirror. In this embodiment the transparent window 64 is located circumferentially around the wall of the housing 42 to reflect radiation out the side of the endoscopic unit 34. In this embodiment the optical fiber 44 does not rotate to create a circulation radiation scan. Instead, the beam director 158 is connected to a flexible rotatable shaft 46' which is connected to the reducing gear 76, or to a direct "in line" linkage, similar to that previously described. Shaft 46' may be housed within protective sheath 47'. The fiber is not connected as in Fig. 6 along the axis but rather is run outside the sheath 47' and outer casing 42 toward the proximal end 45 where it is coupled to interferometer 4. This approach has the added advantage that several optical fibers may be coupled to endoscopic unit 34 and located in the image plane of lens (or lens array) 256 so as to produce several axial or rotational beams that can be scanned and acquired in parallel. In one embodiment each fiber is coupled to a separate imaging system. In another embodiment, the beam director 158 is rotated by micromotors (not shown) resident within the endoscopic unit 34.

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There are several methods in which the window 360 is formed while still maintaining structural integrity of the guidewire 334. One method involves using three or more metal or plastic metering rods that attach the flexible tip 350 to the stationary area 340 of the guidewire. Another method involves using a rigid clear plastic widow that may to sealed to the metal or plastic guide wire at the distal and proximal sides of the window. Alternatively, the hollow flexible shaft housing the rotating fiber 344 may be attached to the inside of the metal guidewire housing 334 or may be left freely floating in the bore 343 of the guidewire 334.

Referring again to Fig. 6, in an alternate embodiment of the invention, the imaging system can be coupled with an ultrasonic system. As shown in this figure, an ultrasonic transducer 61 is located within the housing at the distal tip. The beam director 58 is preferably a prism or mirror having a silvered edge 57 through which optical radiation is transmitted perpendicularly to the structure 14 of interest, as described above. The ultrasonic transducer 61 transmits ultrasonic waves to the silvered edge 57, causing perpendicular impingement on the structure in the direction opposite that of the optical radiation. A lead wire 55 emanates away from the transducer, delivering detected ultrasonic signals to a processing unit (not shown).

Referring to Figs. 13A-13D, shown are examples of two types of scanning approaches of internal body organs. The priority for scanning can be such that longitudinal scanning is interlaced with rotational scanning. Rotational priority scanning is shown in Fig. 13A. In this figure, one rotational scan is substantially completed before longitudinal scanning takes place. As a result, the successive circular scans provide images of successive depth within the structure of interest. This is performed in a discrete fashion in Fig. 13A. Referring to Fig. 13B longitudinal scanning occurs concurrently with rotational scanning. In this manner both scans are synchronized to provide a spiral scan pattern. Longitudinal priority scanning is shown in Fig. 13C. In this figure, one longitudinal scan into the tissue wall is completed before incrementing the rotational scan location. Referring to Fig. 13D, one longitudinal scan is completed as synchronized rotational scanning takes place.

Referring to Fig. 14, shown is an image of a vessel obtained using the system of the present invention. As shown by reference numeral 200 and 210, both the surface of the structure 14 as well as the internal features of the structure 14 can be obtained with the rotational scans performed by the components of the measuring arm 10, and the longitudinal scans performed by the components of the reference arm 8.

compensation system 126 equalizes (to less than the coherence length) the difference in the dispersion of the radiation reflected in the reference arm 188 and measurement arm 110 caused by differences in the path lengths. As shown in this figure, the fiber path lengths from the coupler 106 to the reflector 12 should be approximately equal to the path length from the coupler 106 to the distal end of the endoscopic unit 34. In addition to matching the length of fiber to less than a dispersion length, the dispersion compensation system 126 may include optical elements (not shown) comprising glass to compensate for the nominal dispersion incurred as the light exits the fiber in the endoscopic unit 34, and is guided by optical elements 54 and reflects off of the structure 14 of interest, and reenters the endoscopic unit 34. In all embodiments it is important to minimize stray reflections by using anti-reflective coated optics 56 (or optical unit 54) and fibers 22, 32, 44 as well as angle polished open-ended fibers or fiber connectors (not shown). It is further desirable to separate the reference and signal fiber lengths and connector locations by a few coherence lengths so that there are no coherence interactions from these residual reflections.

Further interferometric detection requires alignment of the reference and signal polarization vectors to maintain polarization sensitivity. If the optical fiber 44 of the measuring arm 110 is moved or heated, or if the structure 14 of interest is birefringent, then signal fading can occur. Polarization preserving fibers or polarizing fibers are one solution to this problem of fiber movement or heating, although they do not compensate for birefringence of the structure 14. In addition, the fibers typically do not precisely maintain polarization, the result of which is a smearing out of the coherence function or loss of signal. The use of a polarization diversity receivers 416 as shown in Fig. 15 compensates for both polarization problems.

Referring to Fig. 15, shown is an embodiment of the interferometer 404 including a polarization diversity receiver 416. Such a receiver 416 employs two polarization diversity detectors 417, 415. Optical radiation reflected from the reference reflector 412 and reflected from the structure 414 under observation are combined by the beam splitter 406, which may comprise an optical coupler in an optical fiber embodiment of the interferometer. Using polarization controllers (not shown) the reference arm 408 polarization is adjusted so as to equally illuminate the two detectors 417, 415 using a polarization beam splitter (PBS) 420. In an embodiment in which this portion of the optical path is in open air, a bulk zero-order waveplate between beamsplitter 406 and reference reflector 412, or other suitable location, can be used. In an embodiment in which an optical fiber is used for this portion of the path, a fiber polarization rotation device (not shown) may be utilized.

polarization rotation within the structure 414 and can provide information about the birefringence of the structure 412 by examining the relative strengths of the two polarization components. The sum of the squared outputs of the two detectors 417, 415 will be independent of the state of polarization of the light reflected from the structure 412. As the interferometric signal in one detector 417 is proportional to the sample electric field in the horizontal polarization, and the signal in the other detector 415 is proportional to the sample electric field in the vertical polarization, the sum of the square of these two electric field components is equal to the total power. It is possible to extend this polarization diversity receiver to a polarization receiver by using additional detectors and waveplates so that the entire stokes parameters or poincare sphere is mapped out on a scale equal to the coherence length as is known to those of ordinary skill in the art.

As stated above, single-mode fibers are typically used to couple light to and from the structure 14. Additionally, a bulk optic probe module, such as a lens is used in the endoscopic unit 34 to couple light to and from the structure 14. Often there exists a tradeoff between longitudinal scanning range (depth-of-field) and rotational resolution as is the case with conventional microscopes. The rotational resolution is proportional to 1/F# and the depth of field is proportional to $(1/F\#)^2$ where F# is the F-number of the imaging system. Thus, achieving high rotational resolution comes at the expense of scanning depth. Referring again to Fig. 7B, for a Gaussian beam the full width half medium (FWHM) confocal distance b, is approximately given by $2\pi\omega_o^2/\lambda$, where ω_o is the e^{-2} beam intensity waist radius, and λ is the source wavelength. Thus, ω_o is very small to maintain good rotational and axial resolution. The imaging depth is also small because light collected outside the confocal distance b (or depth of focus) will not be efficiently coupled back into the optical fiber. For a 20 μm rotational resolution the depth of field is ~ 800 μm at a wavelength of 0.8 μm. Therefore, in one embodiment it is preferred that the optical depth-of-field approximately match the longitudinal range. With the large dynamic range of OCT one can scan beyond the confocal distance and electronically equalize the signal according to the longitudinal point-spread function up to the point where signal to noise or signal to blindness limits the equalization.

radiation emitted at 1.3 um. By taking a ratio of images obtained with the 1.5 um source and the 1.3 um source, the water content of the sample can be determined on a microstructural scale.

As stated above, the application of WDM can enhance the ability to visualize tissue. There are several methods to wavelength multiplex signals in this invention. As shown, a single-mode fiber optic WDM multiplexer 605 for multiplexing multiple optical sources, and WDM demultiplexer 620 for demultiplexing the receiver signals can be utilized. The coupler 606 can be of the fused biconical tapered couplers or bulk interference filter type as is known to be widely commercially available. The only requirement is that the optical fibers used be single-mode over all the wavelength ranges of interest. For the demultiplexing operation, in the embodiment shown, the demultiplexer 620 is coupled to two separate detectors 616, 617. This configuration provides enhanced sensitivity as there is detected shot noise from only one optical wavelength.. An alternative demultiplexer embodiment involves using a single detector (not shown) for separating the signals based on their unique Doppler shift (in longitudinal priority scanning embodiments), or serrodyne frequency shift (in rotational scanning).

NON-LONGITUDINAL SCANNING EMBODIMENTS

Although most of the above discussion has focused on methods that involve changing the length of the reference path through a longitudinal scanning mechanism, there are several embodiments of the present invention which do not employ a longitudinal scanning mechanism, particularly as described in Fig. 17 and Fig. 18. Referring to the embodiment of Fig. 17, the optical radiation source 702 is a narrow bandwidth frequency tunable source, such as a semiconductor laser with tunable external gratings, a tunable solid state laser (e.g. TiAlO3), or a dye laser. As the optical source 702 is tuned rapidly over a wide frequency range, longitudinal information about the structure 714 in question can be determined without the use of a longitudinal scanning mechanism. The radiation emitted by the sources 702 is transmitted to an optical coupler 706 which, as described previously, directs the radiation along an optical path defining the measuring arm 710 including a rotation mechanism 735 coupled to an endoscopic unit 734, and along an optical path defining the reference arm 708, including a dispersion compensation system 726, coupled to a static reference reflector 712. which is static during the measurement interval.

The constant power optical source 702 is rapidly frequency tuned over a wide frequency range in, for example, a sawtooth fashion, thus implementing a frequency chirp. In operation the measuring path 710 length is typically slightly longer than the reference path 708 length.

The output of the optical spectrum analyzer 820 becomes an input signal to a computerized image processor 822 which performs a Fourier transform of the spectrum at each rotational position to achieve an image of the structure in question. The output of the image processor 822 is directed to the display/recording device 838. In operation, the reflected radiation from the optical paths defining the reference arm 808 and measurement arm 810 are combined in the optical coupler 806 as discussed previously and transmitted to the spectrum analyzer 820. In one embodiment, the reference arm 808 path length is slightly less than the path lengths of interest to structure 814.

For purposes of discussion, assume there is a single reflection from within structure 814. Let the measuring arm 810 path length be the optical path length from the source 802 to structure 814 back to the input of the optical spectrum analyzer 820. Let the reference path 808 length be from optical source 802 to reference reflector 812 back to the input of the optical spectrum analyzer 820. The differential optical path length is the difference between the measuring and reference arm 810, 808 paths. The magnitude of the reflection in structure 814 and its associated differential path length can be measured by examining the optical spectrum. For a given differential optical path length there will be constructive and destructive optical interference across the frequencies contained in source 802, at optical spectrum analyzer 820. The magnitude of this interference will be dependent on the magnitude of the reflection. If there is no reflection, then there will be no interference. If the reflection is as large as the reference reflection, then there could be complete cancellation of the optical spectrum at particular frequencies.

In the absence of differential dispersion, which is compensated using dispersion compensator 826, the optical spectrum measured at the optical spectrum analyzer 820 will contain a sinusoidal interference pattern representing intensity versus optical source frequency. The magnitude of the interference pattern is proportional to the structure's reflection coefficient the frequency of which is proportional to the differential optical path length. The period of the interference pattern versus optical frequency is given by $\Delta f \sim \Delta x/c$, where Δx is the differential optical path length. If there are many optical reflections (different Δx's) at different depths within the structure 814, then there will be many sinusoidal frequency components. By performing a Fourier transform in the image processor 822, of the data derived in the optical spectrum analyzer 820 will provide a reflectivity profile of the structure 814.

SYSTEM USE WITH MEDICAL PROCEDURES

The above-described embodiments of the present invention can be used with many types of minimally invasive medical procedures. The present invention can provide a method of

frequency of which is proportional to the differential optical path length. The period of the interference pattern versus optical frequency is given by $\Delta f \sim \Delta x/c$, where Δx is the differential optical path length. If there are many optical reflections (different Δx's) at different depths within the structure 814, then there will be many sinusoidal frequency components. By performing a Fourier transform in the image processor 822, of the data derived in the optical spectrum analyzer 820 will provide a reflectivity profile of the structure 814.

SYSTEM USE WITH MEDICAL PROCEDURES

The above-described embodiments of the present invention can be used with many types of minimally invasive medical procedures. The present invention can provide a method of intravascular high resolution imaging for intravascular stent deployment. The imaging system of the present invention can be integrated into a conventional stent catheter. High resolution imaging can be used to assess the position of the stent relative to the vessel or tissue wall, identify the presence of clot within the vessel or tissue wall, and to determine the effect of compression on vascular microstructure. Stent placement is currently followed with angiograms (as described above) and intravascular ultrasound. The limitations of intravascular ultrasound are the low resolution, lack of ability to distinguish clot from plaque, and inability to accurately assess the microstructure below the vessel or tissue wall.

Referring to Fig. 11A, B, a stent can be partially deployed by balloon 80. If the stent is made transparent or partially transparent then the imaging technique can be used to help place the stent. To help in stent placement and inspection, two or more sheaths or other smooth surfaces can separate torque cable 45 and intimal surface of catheter body 47 so as to allow the imaging apparatus to move along the fiber axis relative to an outer catheter. The outer catheter can be secured using the proximal balloons or other means. The imaging catheter can be manually or in an automated fashion moved to inspect the surface of the stent or produce an image set.

Alternatively, the imaging system of the present invention can be integrated into a conventional pericutaneous atherectomy catheter. Therefore, the movement of the atherectomy blade through the plaque can be monitored in real-time reducing the likelihood of damage to vulnerable structures. Further, high resolution imaging is currently not available to guide conventional rotoblade catheter removal of plaque. The procedure, which 'grinds" the surface of the vessel or tissue, is currently guided with angiography. The low resolution guidance with

7. The apparatus of claim 1, further comprising at least one Faraday circulator for directing radiation to said detector.

8. The apparatus of claim 1, wherein said probe unit comprises at least one rotating optical system to direct optical radiation to said structure, and said fiber is rotatable within said bore.

9. The apparatus of claim 8, further comprising a drive shaft assembly mechanically coupled to said proximal end of said fiber causing rotation thereof.

10. The apparatus of claim 9, wherein a lens is affixed to said fiber and said beam director is coupled to an actuator for altering the direction of the transmitted light in a direction substantially orthogonal to the direction of fiber rotation.

11. The apparatus of claim 8, said rotating optical system comprising a lens located at said distal end of said fiber and positioned to direct light from said optical fiber; and a beam director located adjacent said lens and positioned to direct optical radiation from said lens to said structure.

12. The apparatus of claim 8 wherein said fiber is stationary and said rotating optical system comprises a rotating beam director.

13. The apparatus of claim 1, wherein said coupler comprises at least one optical lens.

14. The apparatus of claim 1, wherein the probe unit further comprises a guidewire.

15. The apparatus of claim 1, wherein said probe unit comprises an endoscope having a transparent window disposed at an end thereof for imaging said structure.

16. The apparatus of claim 15 further comprising at least one inflatable element affixed to a portion of said endoscope.

17. The apparatus of claim 16, said endoscope further comprising at least one port defined therein for performing one of the following: pressure measurement, imaging, fluid injection, and placement of a guidewire.

18. The apparatus of claim 17, wherein said inflatable element is proximal to said at least one port.

19. The apparatus of claim 1, further comprising an artherectomy device coupled to said probe unit.

20. The apparatus of claim 1, further comprising a laser scalpel coupled to said probe unit.

21. The apparatus of claim 1, said probe unit further comprising a trocar.

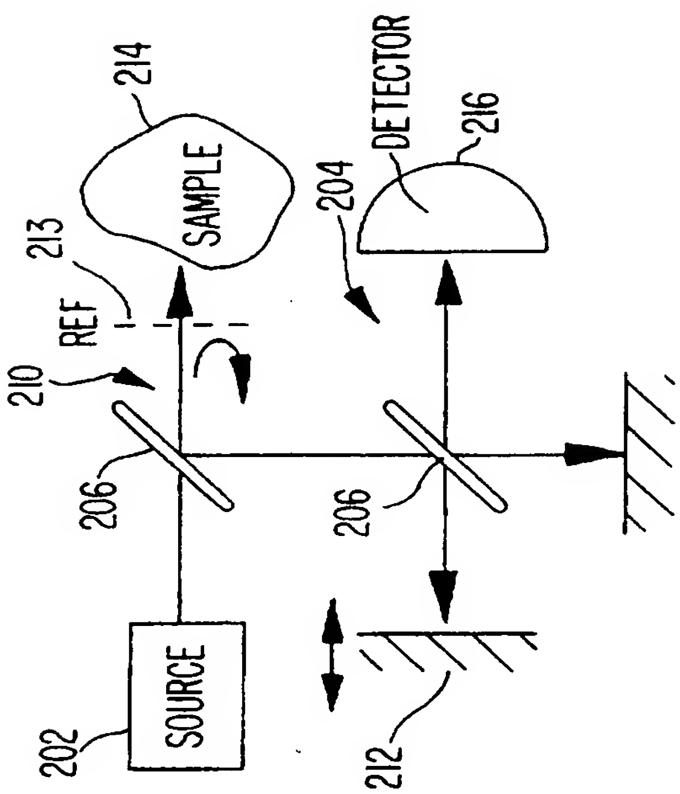
214
SAMPLE
213
REF
210
DETECTOR
216
204
206
206
SOURCE
202
212

FIG. 2B

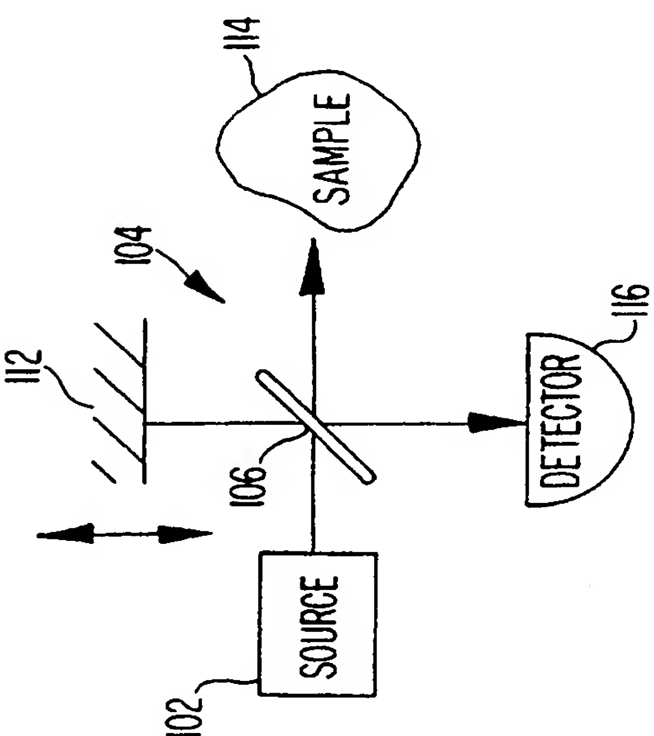
114
SAMPLE
104
112
106
DETECTOR
116
SOURCE
102

FIG. 2A

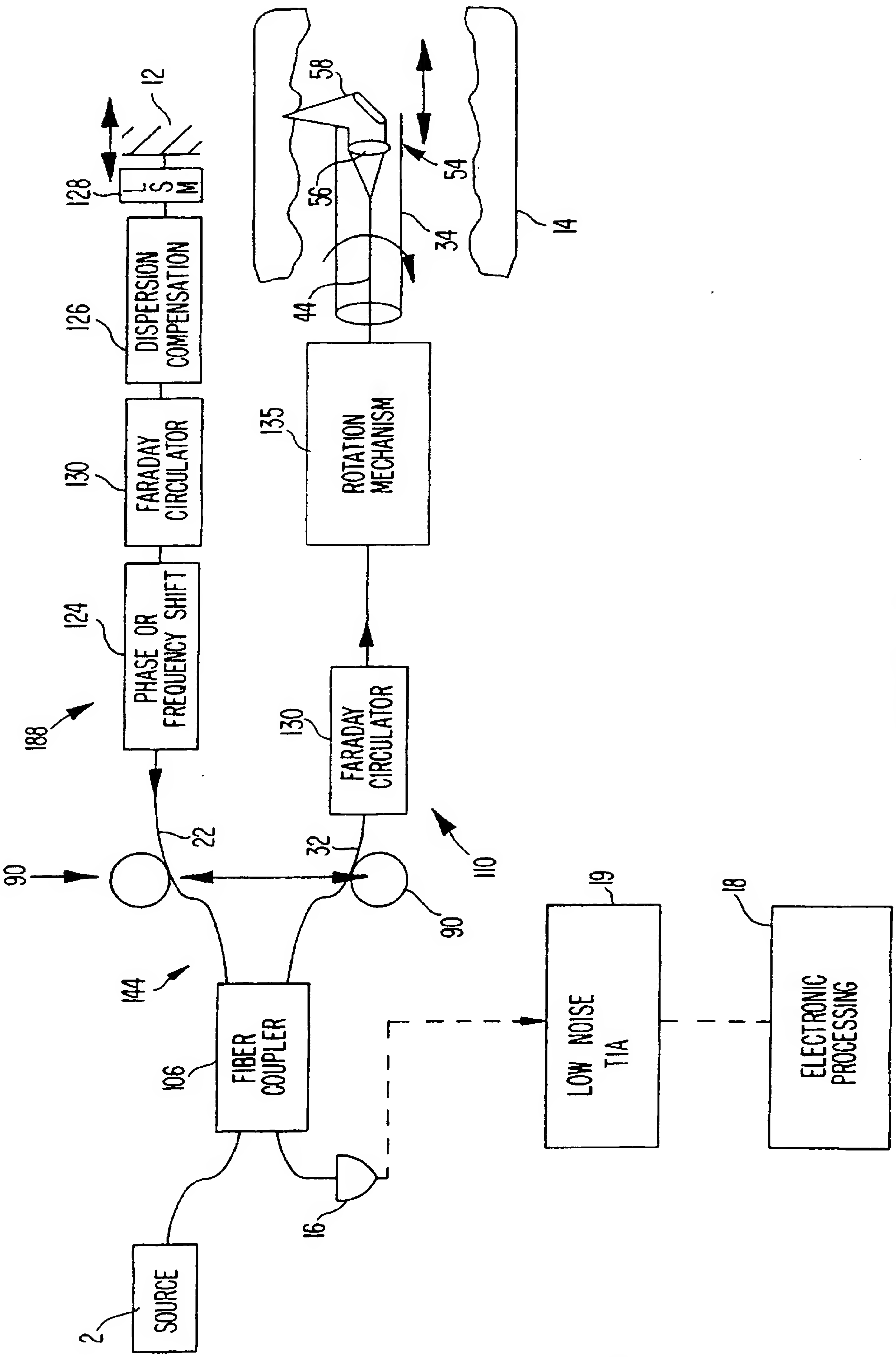
SOURCE
FIBER COUPLER
LOW NOISE TIA
ELECTRONIC PROCESSING
PHASE OR FREQUENCY SHIFT
FARADAY CIRCULATOR
DISPERSION COMPENSATION
L S M
FARADAY CIRCULATOR
ROTATION MECHANISM
2
16
106
144
90
22
32
110
188
124
130
126
128
12
135
44
34
56
54
58
14
19
18

FIG. 4

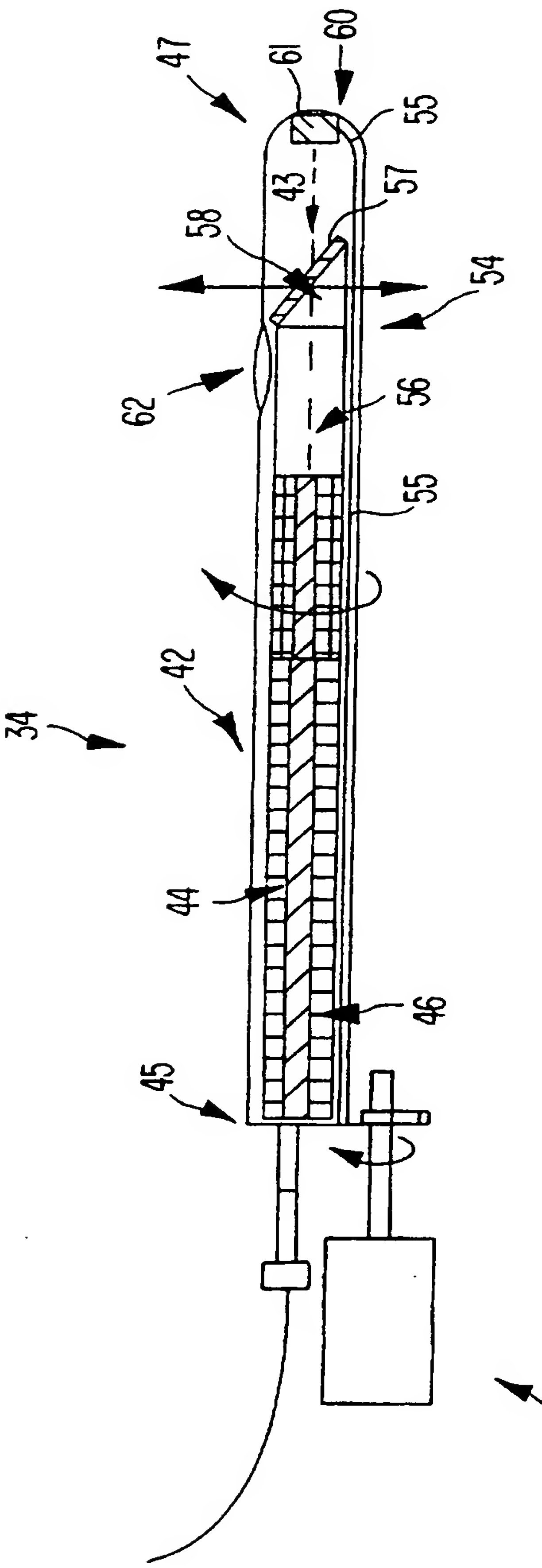

FIG. 6

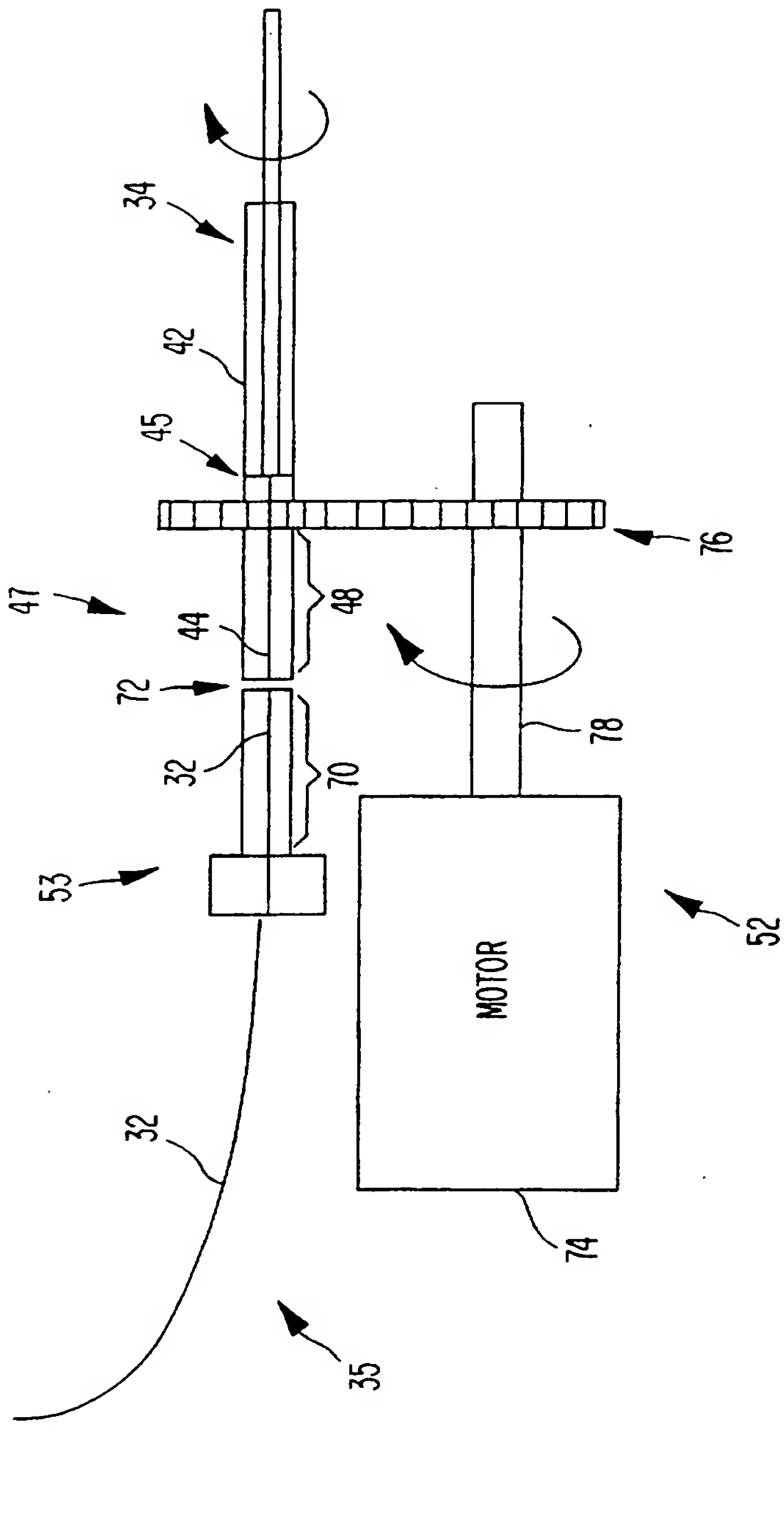

FIG. 8

SUBSTITUTE SHEET (RULE 26)

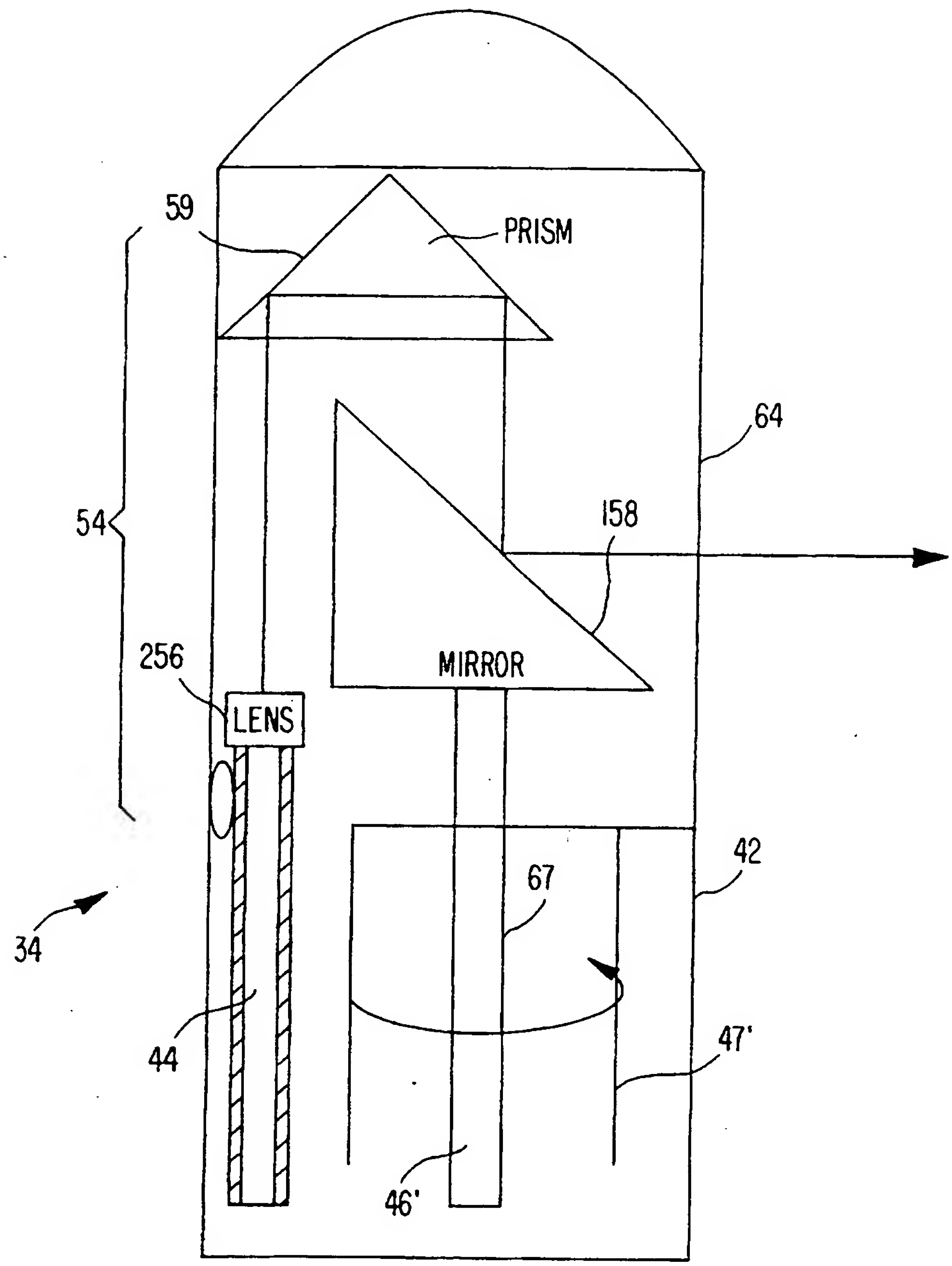

FIG. 10

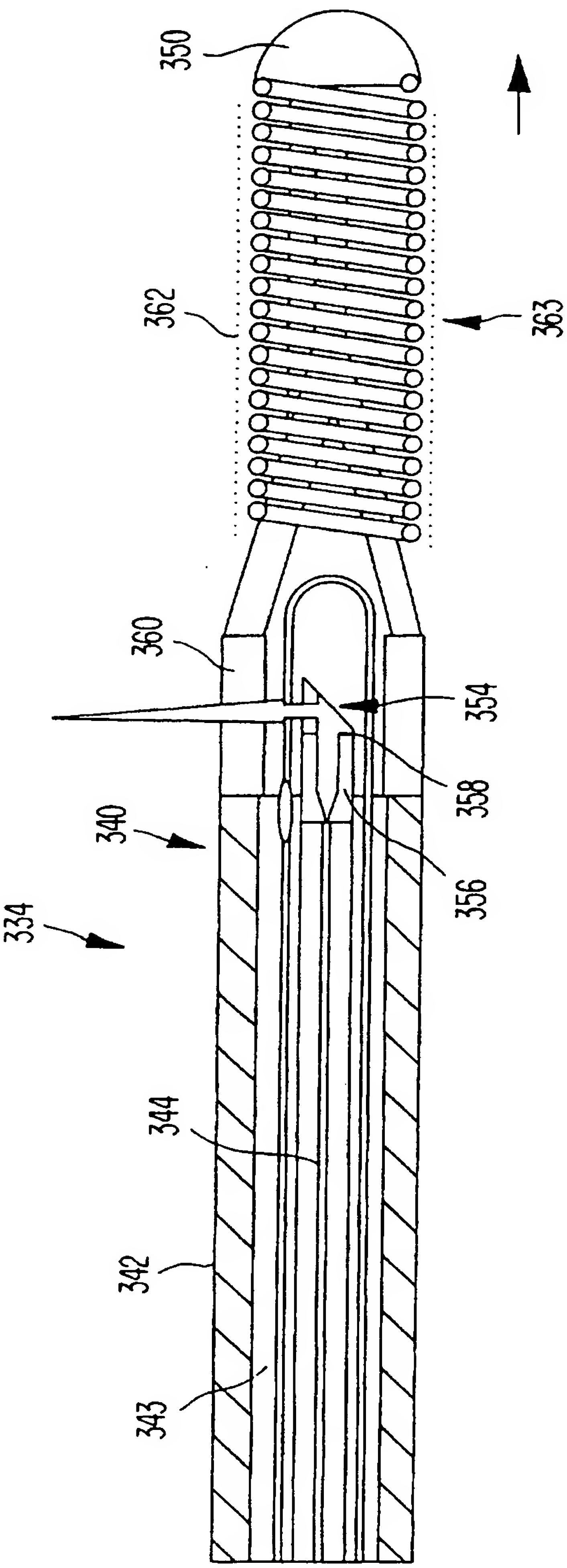

FIG. 12

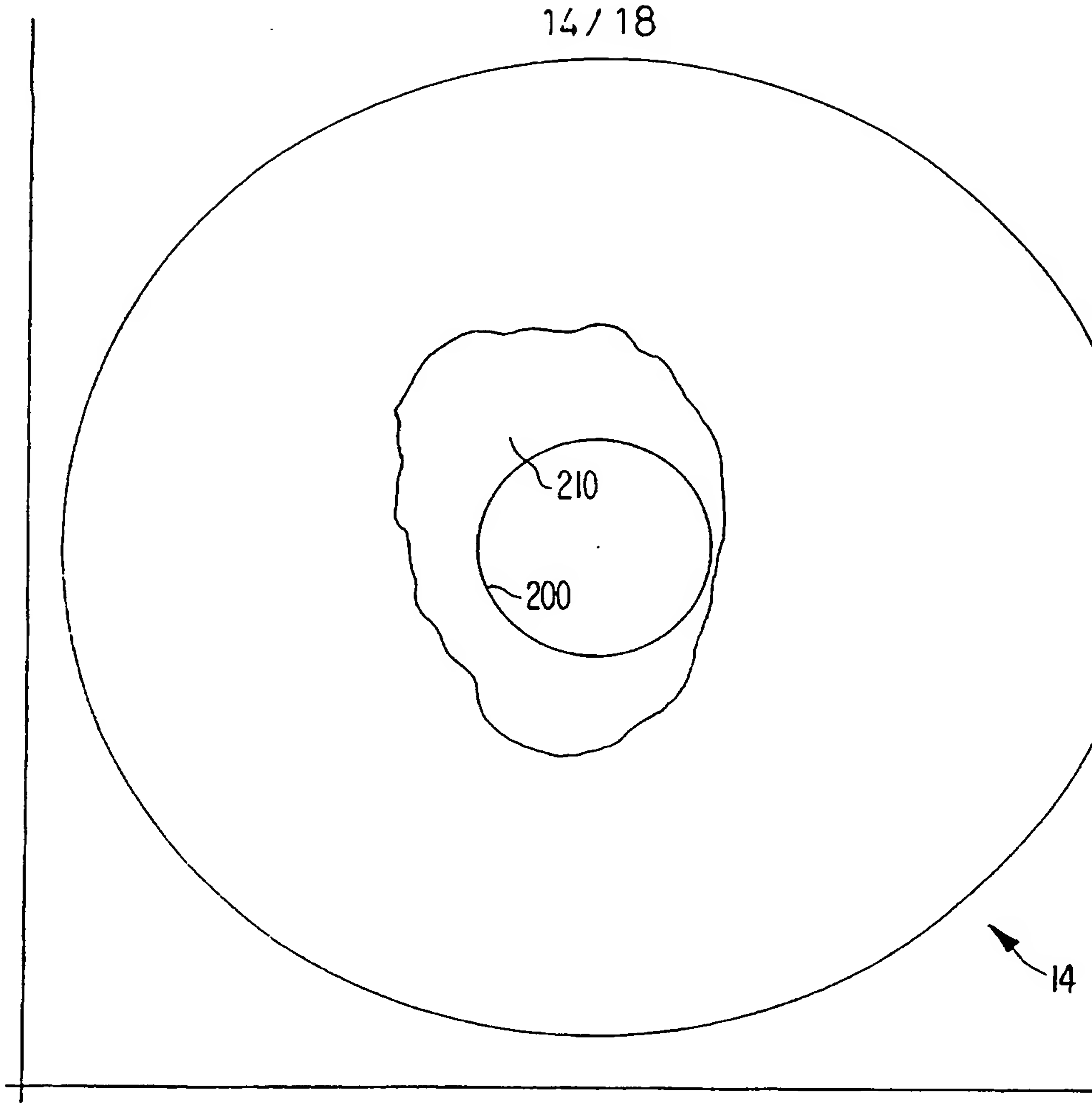
210
200
14

FIG. 14

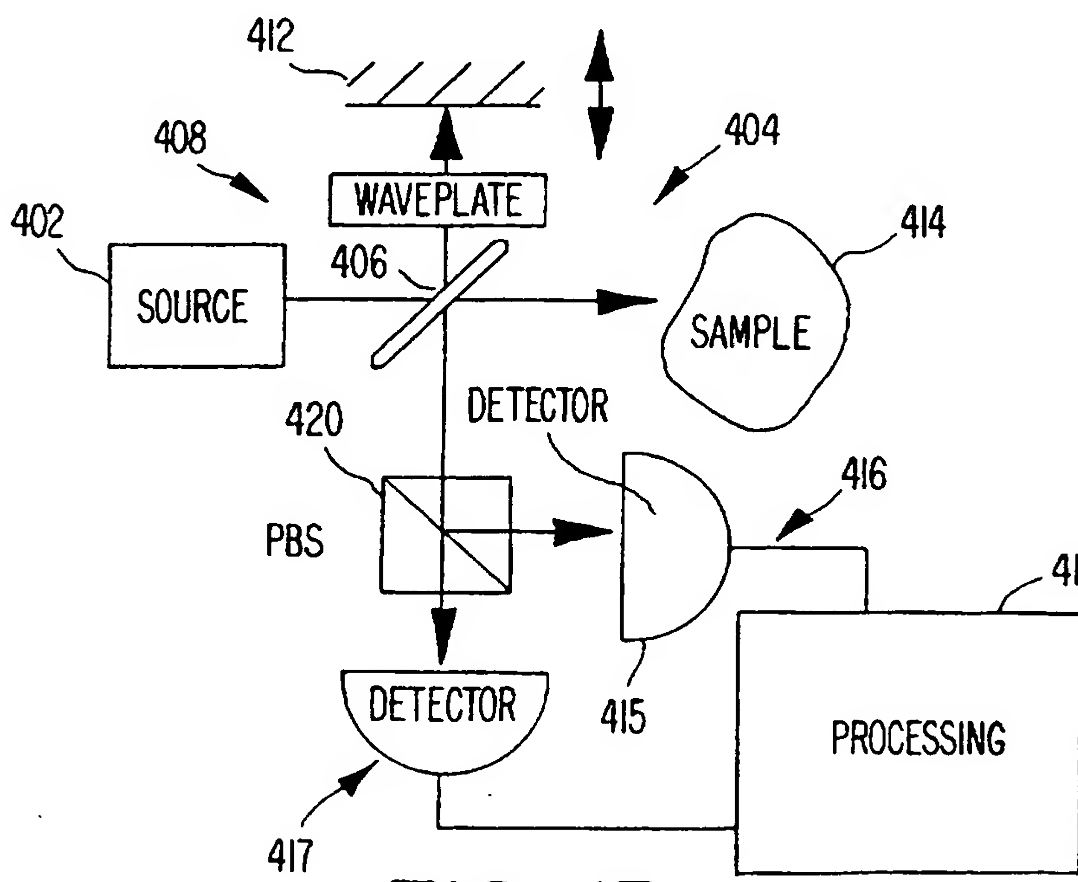
412
408
404
WAVEPLATE
402
414
SOURCE
406
SAMPLE
420
DETECTOR
416
PBS
418
DETECTOR
415
PROCESSING
417

FIG. 15

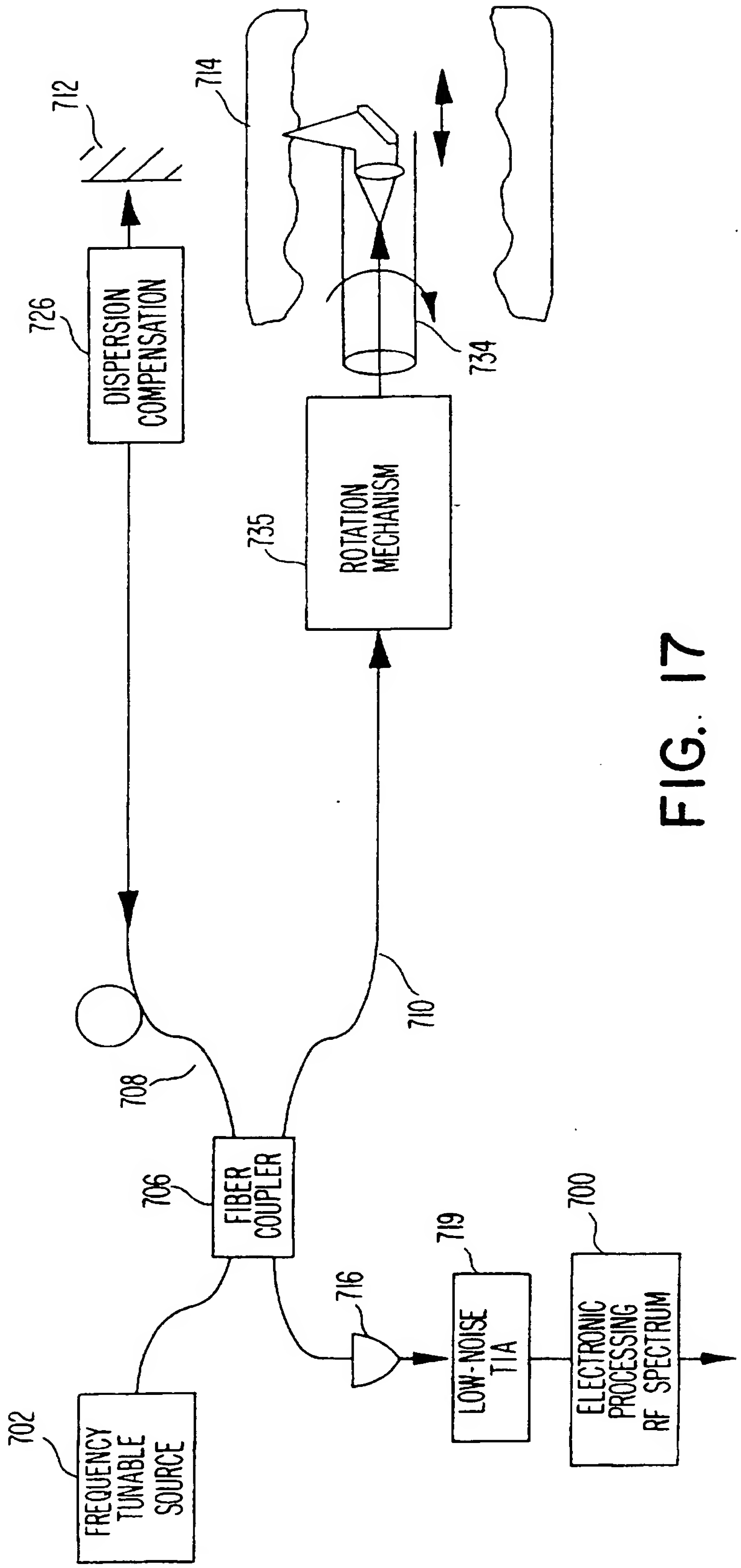
712
714
726
DISPERSION COMPENSATION
734
735
ROTATION MECHANISM
710
708
706
FIBER COUPLER
716
719
LOW-NOISE TIA
700
ELECTRONIC PROCESSING RF SPECTRUM
702
FREQUENCY TUNABLE SOURCE

FIG. 17

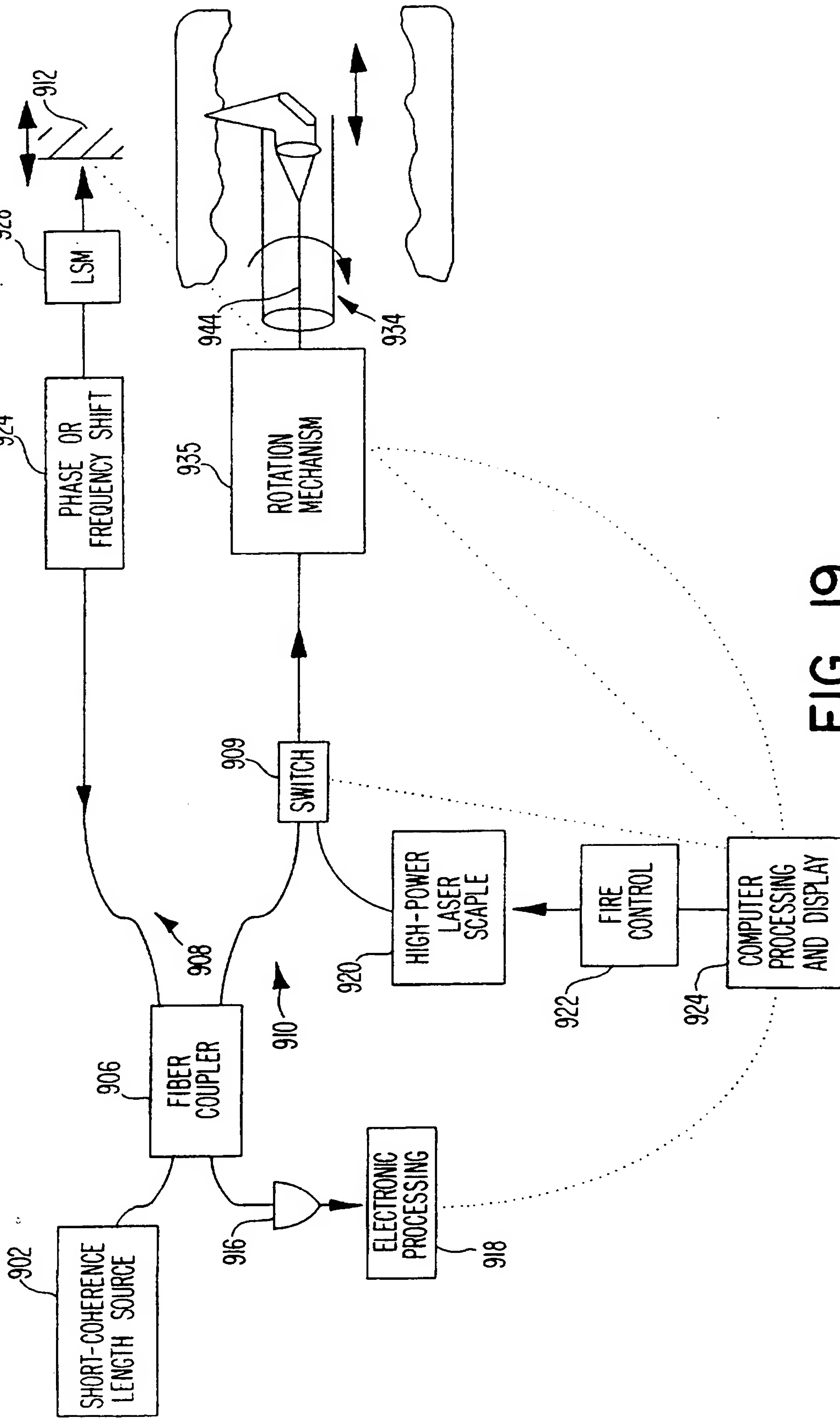
912
928
LSM
924
PHASE OR FREQUENCY SHIFT
944
934
935
ROTATION MECHANISM
909
SWITCH
908
910
906
FIBER COUPLER
920
HIGH-POWER LASER SCAPLE
922
FIRE CONTROL
924
COMPUTER PROCESSING AND DISPLAY
902
SHORT-COHERENCE LENGTH SOURCE
916
ELECTRONIC PROCESSING
918

FIG. 19

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 95 33970 A (MASSACHUSETTS INST TECHNOLOGY) 14 December 1995 cited in the application see the whole document -----	1

1

CORRECTED VERSION*

PCT

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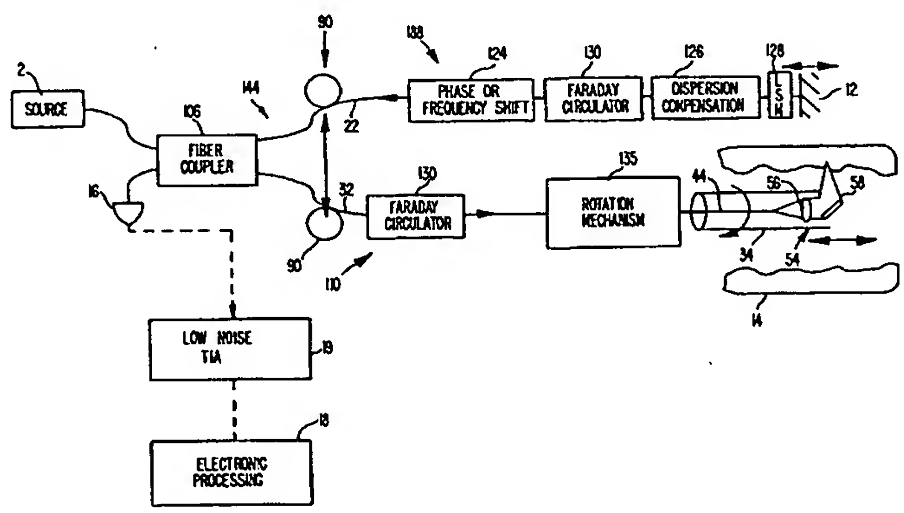
Published
With international search report.

(54) Title: METHOD AND APPARATUS FOR PERFORMING OPTICAL MEASUREMENTS USING A FIBER OPTIC IMAGING GUIDEWIRE, CATHETER OR ENDOSCOPE



(57) Abstract

An imaging system for performing optical coherence tomography includes an optical radiation source; a reference optical reflector; a first optical path leading to the reference optical reflector; and a second optical path coupled to an endoscopic unit. The endoscopic unit preferably includes an elongated housing defining a bore; a rotatable single mode optical fiber having a proximal end and a distal end positioned within and extending the length of the bore of the elongated housing; and an optical system coupled to the distal end of the rotatable single mode optical fiber, positioned to transmit the optical radiation from the single mode optical fiber to the structure and to transmit reflected optical radiation from the structure to the single mode optical fiber. The system further includes a beam divider dividing the optical radiation from the optical radiation source along the first optical path to the reflector and along the second optical path; and a detector positioned to receive reflected optical radiation from the reflector transmitted along the first optical path and reflected optical radiation transmitted from the structure along the second optical path. The detector generates a signal in response to the reflected optical radiation from the reference reflector and the reflected optical radiation from the structure, and a processor generating an image of the structure in response to the signal from the detector. The system provides both rotational and longitudinal scanning of an image.

*(Referred to in PCT Gazette No. 49/1998, Section II)

Method and Apparatus for Performing Optical Measurements using a Fiber Optic Imaging Guidewire, Catheter or Endoscope

Cross-Reference to a Related Application

This application is a continuation in part of U.S. Serial No. 08/492,738, filed on June 21, 1995, pending; and is a continuation in part of 08/577,366, filed on December 22, 1995, pending; and is a continuation in part of U.S. Serial No. 08/252,940, filed on June 2, 1994, pending, which is a continuation in part of 08/033,194, filed on March 16, 1993, now U.S. Patent No. 5,459,570, which is a continuation of 07/692,877, filed on April 29, 1991, now abandoned, the contents of which are all incorporated herein by reference.

Field of Invention

This invention relates to the field of optical imaging and more specifically to the field of medical imaging with interferometric detection.

Background of the Invention

Over the past decade there have been tremendous advances in biomedical imaging technology. For example, magnetic resonance imaging, X-ray computed tomography, ultrasound, and confocal microscopy are all in widespread research and clinical use, and have resulted in fundamental and dramatic improvements in health care. However, there are many situations where existing biomedical diagnostics are not adequate. This is particularly true where high resolution (~ 1 μm) imaging is required. Resolution at this level often requires biopsy and histopathologic examination. While such examinations are among the most powerful medical diagnostic techniques, they are invasive and can be time consuming and costly. Furthermore, in many situations conventional excisional biopsy is not possible. Coronary artery disease, a leading cause of morbidity and mortality, is one important example of a disease where conventional diagnostic excisional biopsy can not be performed. There are many other examples where biopsy can not be performed or conventional imaging techniques lack the sensitivity and resolution for definitive diagnosis.

Moreover, for medical procedures such as balloon angioplasty, conventional techniques have not been able to provide high resolution imaging of the artery while a balloon is being inflated. Many other interventional procedures would greatly benefit from high resolution, in-

housing for delivering fluid to the structure in question. The endoscopic unit can further include one or more inflatable balloons for performing procedures such as balloon angioplasty, for maintaining the opening in a vessel.

The interferometer of the system further includes a beam divider which divides the optical radiation from the optical radiation source along the first optical path to the reflector and along the second optical path to the structure being viewed. The optical radiation detector is positioned to receive reflected optical radiation from the reflector and reflected optical radiation from the structure and to generate a signal in response to the reflected optical radiation. A processor utilizes the signals from the detector to generate an image of the structure being viewed.

In one embodiment the reference optical reflector is typically coupled to a movable actuator to provide periodic movement to the reference mirror. In another embodiment the movable reference mirror is replaced with a static reference mirror and the broadband optical source replaced with a narrow bandwidth frequency tunable source, such as a semiconductor laser with tunable external gratings, a tunable solid state laser, or a dye laser. With such a source, optical radiation reflected from the structure being observed will arrive at the detector after the radiation reflected from the reference mirror is received at the detector. If the source is frequency modulated this delay will result in a beat frequency that is dependent on the difference between the distance from the detector to the reflection site within the structure, and the distance from the detector to the reference reflector. In still other embodiments of the present invention, the detector forming part of the imaging system includes a polarization diversity receiver, or alternatively a polarization analyzer. In still another embodiment the source consists of a broad band optical source, an interferometric detector using an optical spectrum analyzer wherein the Fourier transform of the spectrum is used to derive the reflectance profile of the sample.

It should be noted, that as used herein, the term endoscopic, applies to medical as well as non-medical imaging. One example of non-medical imaging in which the present invention may be used is as a replacement for a borescope to detect faults in cavities and bores in various industrial applications. For purposes of discussion only, the description to follow describes the present invention in terms of medical imaging, but the it is not the intent to limit the applications so described herein. Furthermore although the term endoscope is used, this invention directly relates to guidewires, catheters, and imaging with probes placed through trocars.

Fig. 15 depicts an embodiment of an interferometer of the present invention including a polarization diversity receiver.

Fig. 16 depicts an embodiment of the imaging system of the present invention, utilizing wave division multiplexing.

Fig. 17 depicts a non-longitudinal scanning embodiment of the imaging system of the present invention, utilizing a narrow bandwidth, frequency tunable optical source.

Fig. 18 depicts a non-longitudinal scanning embodiment of the imaging system of the present invention, utilizing a Fourier transform spectroscopy.

Fig. 19 depicts an alternate embodiment of the invention whereby the imaging system of the present invention is integrated with a laser surgical device.

By rotating the optical radiation beam emitted from the endoscopic unit 34, rotational scanning may be accomplished. In rotational scanning, a circumferential path whose radius is centered at the longitudinal axis of the endoscopic unit 34 is viewed.

OPTICAL SOURCES

Considering each component in more detail, the optical source 2 has characteristics such as wavelength, power, coherence length, and autocorrelation function which are important factors in system performance. In some applications, near infrared sources (1.0 - 2.0 um) tend to penetrate deeper into many biological media than visible wavelengths and are therefore preferable. The optical radiation source 2 can include in various embodiments: semiconductor sources (light emitting diodes (LED), edge emitting diodes (ELED), superluminscent diodes (SLD), mode-lock lasers (e.g. $TiAl_2O_3$, $Cr:Mg_2SiO_4$, $CrLiSrAlF_6$), rare earth doped fibers (REDF) (Yb, Nd, Er, Pr, Tm), and super-continuum or Raman sources. For REDF in order to obtain a good coherence length and autocorrelation function, it may be necessary to insert short period Bragg gratings or long period Bragg gratings into the fiber or use filters external to the fiber to shape the Amplified Spontaneous Emission spectrum (ASE). LED and ELED devices are very-low cost broad bandwidth devices having coherence lengths less than 10 μm. Their main limitation is that typically they have very low power (< 100 μW) when coupled into a single spatial mode. SLDs typically have a short coherence length of about ~ 10 μm, and power of about ~ 2 mW. Actively and passively mode-locked lasers offer very high power (> 100 mW) and short coherence length (< 5 μm). Additionally, source powers in excess of 100 mW and coherence lengths under 10 μm can be used. Spectrally shaped REDF, particularly cladding pumped fibers offer good performance in many applications.

INTERFEROMETERS

Referring to Fig.'s 2A and 2B, there are several varieties of interferometers that may be used in the system of the present invention. Although bulk optical and free space implementations are shown in these figures, there exist equivalent embodiments employing optical fibers. One embodiment employs a simple Michelson Interferometer 104, as shown in Fig. 2A. In another embodiment, as shown in Fig. 2B, the interferometer 204 includes a sample reference reflector 213 in the measuring arm 210. The use of this reference reflector 213 in the measuring arm 210 allows for long displacements between beamsplitter 211 and sample 214.

LONGITUDINAL SCANNING MECHANISMS

Referring to Fig. 4, the methods for performing longitudinal scanning are addressed. In order to maintain good detection sensitivity in rotational priority scanning the reference light must be frequency shifted to move the interference signal away from baseband 1/f-type noise and to prevent aliasing using serrodyne techniques with a phase shifter or an acousto-optic frequency shifter 124. In this figure, either a longitudinal scanning mechanism 128 can be used to move the reference reflector 12, or a fiber stretcher 90 can be used to change the path length. The longitudinal scanning mechanism 128 can include for example, a stepper motor, a DC servo-motor, or an electromagnetic speaker coil. The length or extent of movement by the longitudinal scanning mechanism 128 is preferably at least slightly greater than the desired scanned depth range in the structure. The longitudinal scanning mechanism 128 preferably has a velocity at which it moves the reference reflector 12 that is uniform at least during the times when scanning occurs, i.e. a step function. Alternatively the velocity imparted by the longitudinal scanning mechanism 128 may take the form of a ramp or sawtooth function. A movement detector (not shown) can further be coupled to the longitudinal scanning mechanism 128 to detect the position of the reference reflector 12 in order to achieve uniform motion of the reference reflector 12 or to sense the actual velocity profile and correct for the nonuniform velocity in electronic processing unit 18. More specifically, the longitudinal scanning mechanism 128 can be coupled to a uniform motion system (not shown), capable of transmitting a signal indicative of desired position of the reference reflector 12 at each point in the travel path of the reference reflector 12 to be compared against a signal from a position detector (not shown). Any resulting error signal is then utilized to control the longitudinal scanning mechanism 128 to maintain the reference reflector 12 moving at a desired constant velocity.

As shown in the embodiments of Fig.'s 4 and 5A, modulation can be carried out with fast fiber stretching using two piezoelectric transducers (PZT) comprising a piezoelectric modulator-type spool around which the optical fibers are wound. As shown in this figure, both the optical fiber 22 of the reference arm 188 and the optical fiber 32 of the measuring arm 110 can thus be wound around a PZT or around another suitable form that can be expanded or contracted using actuation. Each PZT may be driven out of phase, so that as the PZTs periodically stretch the fibers 22, 32 to change the lengths of the optical paths of the reference 188 and measurement 110

shown) at its distal end 47. Within the bore 43 of the housing 42 resides an optical fiber 44, which is, in one embodiment a flexible single mode optical fiber or a single mode fiberoptic bundle having standard, or polarizing maintaining, or polarizing fibers to insure good polarization mode matching. The optical fiber 44 is preferably encased in a hollow flexible shaft 46. As the endoscopic unit 34 both illuminates and collects retroreflected light the optical fiber 44 is preferably a single mode optical fiber. The use of a single mode fiber is preferable for applications of OCT imaging because it will propagate and collect a single transverse spatial mode optical beam which can be focused to its minimum spot size (the diffraction limit) for a desired application. Preferably the single mode optical fiber 44 consists of a core, a cladding, and a jacket (not shown). The radiation beam is typically guided within the glass core of the fiber 44 which is typically 5 - 9 microns in diameter. The core of the fiber is typically surrounded by a glass cladding (not shown) in order to both facilitate light guiding as well as to add mechanical strength to the fiber 44. The cladding of the fiber is typically 125 microns in diameter.

An irrigation port 62 is formed near the distal end 47 of the housing 42 for irrigating the structure being imaged. The rotational scanning mechanism 35 causes rotation of the optical fiber 44 or a component of an optical system 54 disposed at the distal end 47 of the optical fiber 44. The housing 42 includes a transparent window 60 formed in the area of the distal end 47 and adjacent the optical system 54 for transmitting optical radiation to the structure 14 being imaged. The rotational scanning mechanism 35 enables the optical radiation to be disposed in a circular scan. When combined with longitudinal scanning, as described above, the imaging depth of the optical radiation is changed, as further described below.

Referring to Fig. 7A, the optical radiation beam can be emitted out of the distal end of the endoscopic unit 34 or out of the side of the endoscopic unit 34 at an angle, ϕ, to the axis of the endoscopic unit 34. The beam emission direction is scanned rotationally by varying its angle of emission, θ, along the axis of the endoscopic unit 34. The optical radiation beam can further be directed at an angle, ϕ, which deviates from 90 degrees. This facilitates imaging slightly ahead of the distal end of the endoscopic unit 34. In this implementation, the emitted beam scans a pattern which is conical. with a conical angle of 2ϕ. When used with longitudinal scanning, this scan pattern generates a cross sectional image corresponding to a conical section through the artery or vessel or tissue, as further shown in Fig 14. The angle ϕ may be adjustable, as to cam be responsive to control signals from signal processing and control electronics 18 or manually adjustable. Due to the adjustability of the angle, nearly all forward imaging, mainly transverse

replaced with each patient. In addition to these means of coupling, additional modifications for high-speed optical imaging are possible. Either standard or gradient index (GRIN) lenses (not shown) can be used to couple light from the fixed to rotating portion of the catheter. Because more optical elements are involved, alignment of all components to the high tolerances (< 1 mrad angular tolerance) are required for adequate coupling.

The optical connector 48 functions as the drive shaft for the endoscopic unit 34, as the rotation mechanism is coupled thereto. The rotation mechanism includes a DC or AC drive motor 74 and a gear mechanism 76 having predetermined gear ratios. The gear mechanism 76 is coupled to the motor 74 via a shaft 78. In all embodiments, upon activation of the drive motor 74, the shaft 78 rotates causing the gear mechanism 76 and the rotatable optical fiber 44 or a component of the optical system 54 to rotate. Alternatively, the DC drive motor 74 can be a micromotor (not shown) disposed at the distal end of housing, connected to optical system 54 causing rotation or translation of a component of the optical system 54 as further described in Fig. 10.

In embodiments where a fiber is not rotated but a component of the optical system is rotated via a flexible coupling mechanism alternative drive mechanisms to those shown in Fig. 6 and Fig. 8 are possible. Among these drive mechanisms are an "in-line" drive analogous to a drill wherein shaft 78 directly links "in line" with flexible shaft 46. A stationary sheath is used outside shaft 46 to protect fibers which are routed between the sheath and the housing 42.

The optical system 54 can include a number of different optical components depending on the type of scan desired. Referring again to the embodiment of Fig. 6, the optical system 54 includes a lens 56 and an optical beam director 58. The beam director 58 may include a lens, prism, or mirror constructed so as to minimize the effects of turbulence on the beam propagation. In this embodiment, the beam director 58 is preferably a mirror or prism affixed to a GRIN lens 56 for directing optical radiation perpendicularly to the axis of the endoscopic unit 34. The housing 42 includes a transparent window 60 formed along the wall of the endoscopic unit 34. In this embodiment the scan of Fig. 7C is achieved, as the optical radiation is directed perpendicularly through the transparent window 60 and onto the structure 14 of interest.

Referring to Fig. 6, in this embodiment, it is seen that by removing ultrasound components 61 and beam director prism or mirror element, high resolution imaging is possible if the endoscopic unit 34 has a window 160 at the tip of the endoscopic unit 34. In this embodiment the optical system includes a beam director which is a lens 156, which transmits light in a circular path

ribbed sleeve (not shown) or grooves (not shown) in sheath 1180. Although the sheath 1180 is tightly torsionally coupled, it is allowed to slide axially and is driven by linear motor 1181 with suitable coupling means to two plates 1182 affixed to the sheath 1180. Thus, as the motor 1174 drives torque cable 1146 in rotation, the linear motor 1181 can drive the sheath 1180 axially. At the distal end of the endoscopic unit is a mirror beam directing optic 1158. This mirror is hinged in two ways. One hinge 1176 is connected to torque cable 1146 in a torsionally stiff way to drive the mirror in rotation. Another single hinge point 1177 is connected to sheath 1180 so as to drive the mirror in tip and tilt in response to motor 1181. Housing 1142 is suitably metered off of sheath 1180 so as to protect mirror 1177 from contacting the outer the housing 1142. In another embodiment sheath 1180 is directly affixed to torque cable 1146 and the mirror 1158 is replaced with prism beam director attached directly to lens 1156. Gearing mechanism is suitably made to allow motor 1181 to axially drive the entire endoscopic imaging unit in the axial direction. These example embodiments enable beam 1199 to perform automated three dimensional maps of the sample of interest.

Another alternative embodiment of the endoscopic unit 34 of the present invention is shown in Fig. 10. In this embodiment, the optical system 54 preferably comprises a lens 256, a retroreflector such as a prism 59, and a beam director 158 such as a mirror. In this embodiment the transparent window 64 is located circumferentially around the wall of the housing 42 to reflect radiation out the side of the endoscopic unit 34. In this embodiment the optical fiber 44 does not rotate to create a circulation radiation scan. Instead, the beam director 158 is connected to a flexible rotatable shaft 46' which is connected to the reducing gear 76, or to a direct "in line" linkage, similar to that previously described. Shaft 46' may be housed within protective sheath 47'. The fiber is not connected as in Fig. 6 along the axis but rather is run outside the sheath 47' and outer casing 42 toward the proximal end 45 where it is coupled to interferometer 4. This approach has the added advantage that several optical fibers may be coupled to endoscopic unit 34 and located in the image plane of lens (or lens array) 256 so as to produce several axial or rotational beams that can be scanned and acquired in parallel. In one embodiment each fiber is coupled to a separate imaging system. In another embodiment, the beam director 158 is rotated by micromotors (not shown) resident within the endoscopic unit 34.

There are several methods in which the window 360 is formed while still maintaining structural integrity of the guidewire 334. One method involves using three or more metal or plastic metering rods that attach the flexible tip 350 to the stationary area 340 of the guidewire. Another method involves using a rigid clear plastic widow that may to sealed to the metal or plastic guide wire at the distal and proximal sides of the window. Alternatively, the hollow flexible shaft housing the rotating fiber 344 may be attached to the inside of the metal guidewire housing 334 or may be left freely floating in the bore 343 of the guidewire 334.

Referring again to Fig. 6, in an alternate embodiment of the invention, the imaging system can be coupled with an ultrasonic system. As shown in this figure, an ultrasonic transducer 61 is located within the housing at the distal tip. The beam director 58 is preferably a prism or mirror having a silvered edge 57 through which optical radiation is transmitted perpendicularly to the structure 14 of interest, as described above. The ultrasonic transducer 61 transmits ultrasonic waves to the silvered edge 57, causing perpendicular impingement on the structure in the direction opposite that of the optical radiation. A lead wire 55 emanates away from the transducer, delivering detected ultrasonic signals to a processing unit (not shown).

Referring to Figs. 13A-13D, shown are examples of two types of scanning approaches of internal body organs. The priority for scanning can be such that longitudinal scanning is interlaced with rotational scanning. Rotational priority scanning is shown in Fig. 13A. In this figure, one rotational scan is substantially completed before longitudinal scanning takes place. As a result, the successive circular scans provide images of successive depth within the structure of interest. This is performed in a discrete fashion in Fig. 13A. Referring to Fig. 13B longitudinal scanning occurs concurrently with rotational scanning. In this manner both scans are synchronized to provide a spiral scan pattern. Longitudinal priority scanning is shown in Fig. 13C. In this figure, one longitudinal scan into the tissue wall is completed before incrementing the rotational scan location. Referring to Fig. 13D, one longitudinal scan is completed as synchronized rotational scanning takes place.

Referring to Fig. 14, shown is an image of a vessel obtained using the system of the present invention. As shown by reference numeral 200 and 210, both the surface of the structure 14 as well as the internal features of the structure 14 can be obtained with the rotational scans performed by the components of the measuring arm 10, and the longitudinal scans performed by the components of the reference arm 8.

compensation system 126 equalizes (to less than the coherence length) the difference in the dispersion of the radiation reflected in the reference arm 188 and measurement arm 110 caused by differences in the path lengths. As shown in this figure, the fiber path lengths from the coupler 106 to the reflector 12 should be approximately equal to the path length from the coupler 106 to the distal end of the endoscopic unit 34. In addition to matching the length of fiber to less than a dispersion length, the dispersion compensation system 126 may include optical elements (not shown) comprising glass to compensate for the nominal dispersion incurred as the light exits the fiber in the endoscopic unit 34, and is guided by optical elements 54 and reflects off of the structure 14 of interest, and reenters the endoscopic unit 34. In all embodiments it is important to minimize stray reflections by using anti-reflective coated optics 56 (or optical unit 54) and fibers 22, 32, 44 as well as angle polished open-ended fibers or fiber connectors (not shown). It is further desirable to separate the reference and signal fiber lengths and connector locations by a few coherence lengths so that there are no coherence interactions from these residual reflections.

Further interferometric detection requires alignment of the reference and signal polarization vectors to maintain polarization sensitivity. If the optical fiber 44 of the measuring arm 110 is moved or heated, or if the structure 14 of interest is birefringent, then signal fading can occur. Polarization preserving fibers or polarizing fibers are one solution to this problem of fiber movement or heating, although they do not compensate for birefringence of the structure 14. In addition, the fibers typically do not precisely maintain polarization, the result of which is a smearing out of the coherence function or loss of signal. The use of a polarization diversity receivers 416 as shown in Fig. 15 compensates for both polarization problems.

Referring to Fig. 15, shown is an embodiment of the interferometer 404 including a polarization diversity receiver 416. Such a receiver 416 employs two polarization diversity detectors 417, 415. Optical radiation reflected from the reference reflector 412 and reflected from the structure 414 under observation are combined by the beam splitter 406, which may comprise an optical coupler in an optical fiber embodiment of the interferometer. Using polarization controllers (not shown) the reference arm 408 polarization is adjusted so as to equally illuminate the two detectors 417, 415 using a polarization beam splitter (PBS) 420. In an embodiment in which this portion of the optical path is in open air, a bulk zero-order waveplate between beamsplitter 406 and reference reflector 412, or other suitable location, can be used. In an embodiment in which an optical fiber is used for this portion of the path, a fiber polarization rotation device (not shown) may be utilized.

polarization rotation within the structure 414 and can provide information about the birefringence of the structure 412 by examining the relative strengths of the two polarization components.. The sum of the squared outputs of the two detectors 417, 415 will be independent of the state of polarization of the light reflected from the structure 412. As the interferometric signal in one detector 417 is proportional to the sample electric field in the horizontal polarization, and the signal in the other detector 415 is proportional to the sample electric field in the vertical polarization, the sum of the square of these two electric field components is equal to the total power. It is possible to extend this polarization diversity receiver to a polarization receiver by using additional detectors and waveplates so that the entire stokes parameters or poincare sphere is mapped out on a scale equal to the coherence length as is known to those of ordinary skill in the art.

As stated above, single-mode fibers are typically used to couple light to and from the structure 14 . Additionally, a bulk optic probe module, such as a lens is used in the endoscopic unit 34 to couple light to and from the structure 14. Often there exists a tradeoff between longitudinal scanning range (depth-of-field) and rotational resolution as is the case with conventional microscopes. The rotational resolution is proportional to 1/F# and the depth of field is proportional to $(1/F\#)^2$ where F# is the F-number of the imaging system. Thus, achieving high rotational resolution comes at the expense of scanning depth. Referring again to Fig. 7B, for a Gaussian beam the full width half medium (FWHM) confocal distance b, is approximately given by $2\pi\omega_0^2/\lambda$, where ω_0 is the e^{-2} beam intensity waist radius, and λ is the source wavelength. Thus, ω_0 is very small to maintain good rotational and axial resolution. The imaging depth is also small because light collected outside the confocal distance b (or depth of focus) will not be efficiently coupled back into the optical fiber. For a 20 μm rotational resolution the depth of field is ~ 800 μm at a wavelength of 0.8 μm. Therefore, in one embodiment it is preferred that the optical depth-of-field approximately match the longitudinal range. With the large dynamic range of OCT one can scan beyond the confocal distance and electronically equalize the signal according to the longitudinal point-spread function up to the point where signal to noise or signal to blindness limits the equalization.

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ISA/EP

radiation emitted at 1.3 um. By taking a ratio of images obtained with the 1.5 um source and the 1.3 um source, the water content of the sample can be determined on a microstructural scale.

As stated above, the application of WDM can enhance the ability to visualize tissue. There are several methods to wavelength multiplex signals in this invention. As shown, a single-mode fiber optic WDM multiplexer 605 for multiplexing multiple optical sources, and WDM demultiplexer 620 for demultiplexing the receiver signals can be utilized. The coupler 606 can be of the fused biconical tapered couplers or bulk interference filter type as is known to be widely commercially available. The only requirement is that the optical fibers used be single-mode over all the wavelength ranges of interest. For the demultiplexing operation, in the embodiment shown, the demultiplexer 620 is coupled to two separate detectors 616, 617. This configuration provides enhanced sensitivity as there is detected shot noise from only one optical wavelength.. An alternative demultiplexer embodiment involves using a single detector (not shown) for separating the signals based on their unique Doppler shift (in longitudinal priority scanning embodiments), or serrodyne frequency shift (in rotational scanning).

NON-LONGITUDINAL SCANNING EMBODIMENTS

Although most of the above discussion has focused on methods that involve changing the length of the reference path through a longitudinal scanning mechanism, there are several embodiments of the present invention which do not employ a longitudinal scanning mechanism, particularly as described in Fig. 17 and Fig. 18. Referring to the embodiment of Fig. 17, the optical radiation source 702 is a narrow bandwidth frequency tunable source, such as a semiconductor laser with tunable external gratings, a tunable solid state laser (e.g. TiAlO3), or a dye laser. As the optical source 702 is tuned rapidly over a wide frequency range, longitudinal information about the structure 714 in question can be determined without the use of a longitudinal scanning mechanism. The radiation emitted by the sources 702 is transmitted to an optical coupler 706 which, as described previously, directs the radiation along an optical path defining the measuring arm 710 including a rotation mechanism 735 coupled to an endoscopic unit 734, and along an optical path defining the reference arm 708, including a dispersion compensation system 726, coupled to a static reference reflector 712. which is static during the measurement interval.

The constant power optical source 702 is rapidly frequency tuned over a wide frequency range in, for example, a sawtooth fashion, thus implementing a frequency chirp. In operation the measuring path 710 length is typically slightly longer than the reference path 708 length.

The output of the optical spectrum analyzer 820 becomes an input signal to a computerized image processor 822 which performs a Fourier transform of the spectrum at each rotational position to achieve an image of the structure in question. The output of the image processor 822 is directed to the display/recording device 838. In operation, the reflected radiation from the optical paths defining the reference arm 808 and measurement arm 810 are combined in the optical coupler 806 as discussed previously and transmitted to the spectrum analyzer 820. In one embodiment, the reference arm 808 path length is slightly less than the path lengths of interest to structure 814.

For purposes of discussion, assume there is a single reflection from within structure 814. Let the measuring arm 810 path length be the optical path length from the source 802 to structure 814 back to the input of the optical spectrum analyzer 820. Let the reference path 808 length be from optical source 802 to reference reflector 812 back to the input of the optical spectrum analyzer 820. The differential optical path length is the difference between the measuring and reference arm 810, 808 paths. The magnitude of the reflection in structure 814 and its associated differential path length can be measured by examining the optical spectrum. For a given differential optical path length there will be constructive and destructive optical interference across the frequencies contained in source 802, at optical spectrum analyzer 820. The magnitude of this interference will be dependent on the magnitude of the reflection. If there is no reflection, then there will be no interference. If the reflection is as large as the reference reflection, then there could be complete cancellation of the optical spectrum at particular frequencies.

In the absence of differential dispersion, which is compensated using dispersion compensator 826, the optical spectrum measured at the optical spectrum analyzer 820 will contain a sinusoidal interference pattern representing intensity versus optical source frequency. The magnitude of the interference pattern is proportional to the structure's reflection coefficient the frequency of which is proportional to the differential optical path length. The period of the interference pattern versus optical frequency is given by $\Delta f \sim \Delta x/c$, where Δx is the differential optical path length. If there are many optical reflections (different Δx's) at different depths within the structure 814, then there will be many sinusoidal frequency components. By performing a Fourier transform in the image processor 822, of the data derived in the optical spectrum analyzer 820 will provide a reflectivity profile of the structure 814.

SYSTEM USE WITH MEDICAL PROCEDURES

The above-described embodiments of the present invention can be used with many types of minimally invasive medical procedures. The present invention can provide a method of

frequency of which is proportional to the differential optical path length. The period of the interference pattern versus optical frequency is given by $\Delta f \sim \Delta x/c$, where Δx is the differential optical path length. If there are many optical reflections (different Δx's) at different depths within the structure 814, then there will be many sinusoidal frequency components. By performing a Fourier transform in the image processor 822, of the data derived in the optical spectrum analyzer 820 will provide a reflectivity profile of the structure 814.

SYSTEM USE WITH MEDICAL PROCEDURES

The above-described embodiments of the present invention can be used with many types of minimally invasive medical procedures. The present invention can provide a method of intravascular high resolution imaging for intravascular stent deployment. The imaging system of the present invention can be integrated into a conventional stent catheter. High resolution imaging can be used to assess the position of the stent relative to the vessel or tissue wall, identify the presence of clot within the vessel or tissue wall, and to determine the effect of compression on vascular microstructure. Stent placement is currently followed with angiograms (as described above) and intravascular ultrasound. The limitations of intravascular ultrasound are the low resolution, lack of ability to distinguish clot from plaque, and inability to accurately assess the microstructure below the vessel or tissue wall.

Referring to Fig. 11A, B, a stent can be partially deployed by balloon 80. If the stent is made transparent or partially transparent then the imaging technique can be used to help place the stent. To help in stent placement and inspection, two or more sheaths or other smooth surfaces can separate torque cable 45 and intimal surface of catheter body 47 so as to allow the imaging apparatus to move along the fiber axis relative to an outer catheter. The outer catheter can be secured using the proximal balloons or other means. The imaging catheter can be manually or in an automated fashion moved to inspect the surface of the stent or produce an image set.

Alternatively, the imaging system of the present invention can be integrated into a conventional pericutaneous atherectomy catheter. Therefore, the movement of the atherectomy blade through the plaque can be monitored in real-time reducing the likelihood of damage to vulnerable structures. Further, high resolution imaging is currently not available to guide conventional rotoblade catheter removal of plaque. The procedure, which 'grinds" the surface of the vessel or tissue, is currently guided with angiography. The low resolution guidance with

Claims

1. An apparatus for performing imaging of a structure in situ comprising:

an optical radiation source;

an interferometer coupled to said optical radiation source; said interferometer comprising a reference optical reflector, a means for combining optical radiation and a probe unit; said probe unit comprising:

an elongated housing defining a bore; at least one optical fiber, said optical fiber having a proximal end and a distal end positioned within and extending the length of said bore of said elongated housing;

a coupler coupling said optical radiation source to said proximal end of said fiber;

an optical system coupled to said distal end of said optical fiber, and positioned to transmit said optical radiation from said fiber to a structure and to transmit reflected optical radiation from said structure to said distal end of said optical fiber;

a beam director directing said transmitted optical radiation from said distal end of fiber;

a detector generating a signal in response to optical radiation reflected from said reference reflector and optical radiation reflected from said structure; and

a processor generating an image of said structure in response to said signal from said detector,

wherein said means for combining optical radiation, receives and combines optical radiation from said reference reflector and said structure and directs combined light to said detector.

2. The apparatus of claim 1, further comprising an actuator for moving said reference reflector thereby altering the relative distance between said reference reflector and said structure to produce depth- resolved images of the structure.

3. The apparatus of claim 1, wherein said detector comprises of an optical spectrum analyzer, and said processor receives signals from said optical spectrum analyzer and produces depth-resolved images of said structure using said signals.

4. The apparatus of claim 1, wherein said optical radiation source is a narrow-bandwidth frequency tunable source periodically tuned over a determined frequency range.

5. The apparatus of claim 1, wherein said processor performs a real-time frame-to-frame stabilization to reduce motion induced artifacts in an image of said structure.

6. The apparatus of claim 1, said probe unit further comprising an ultrasound transducer.

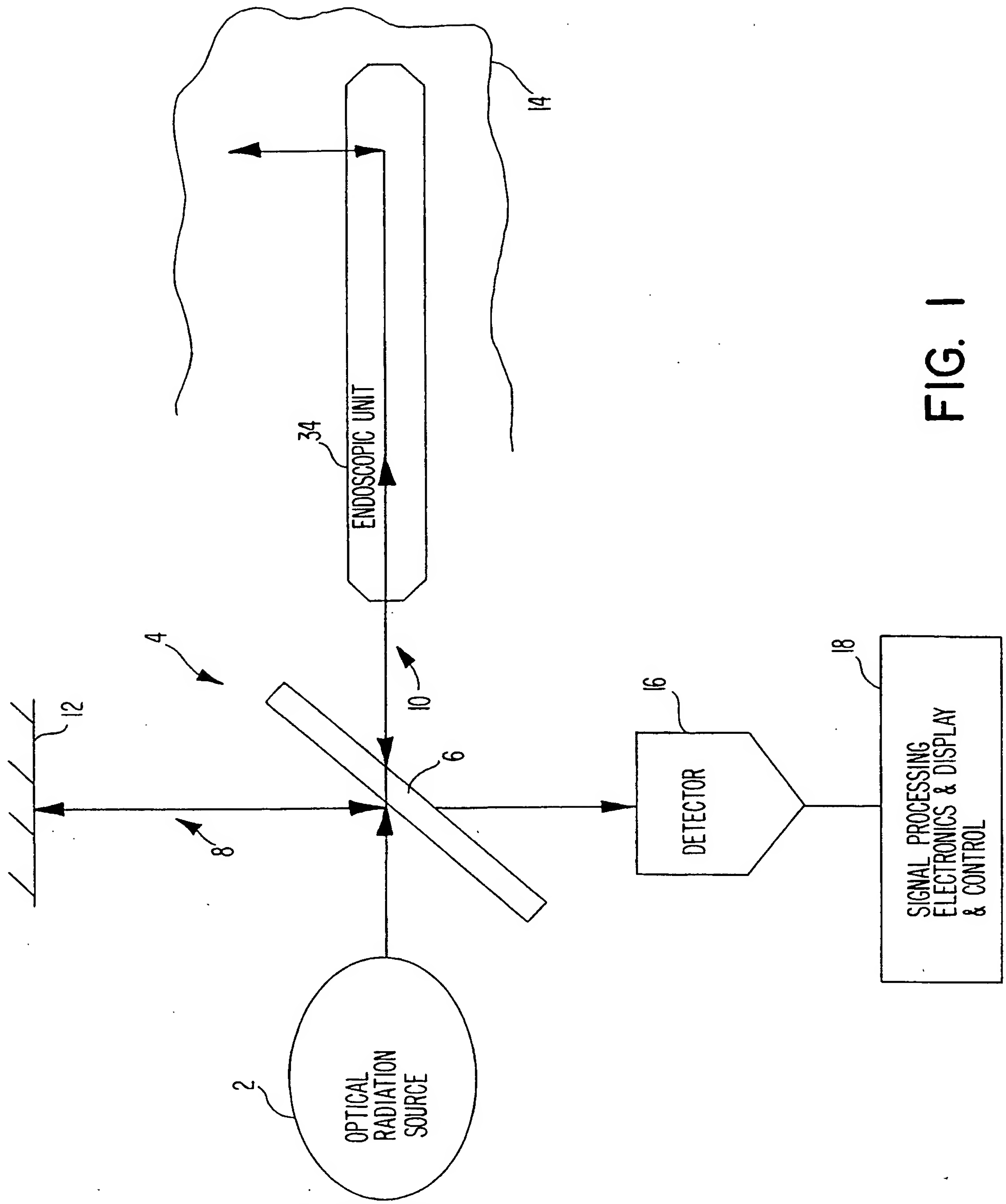
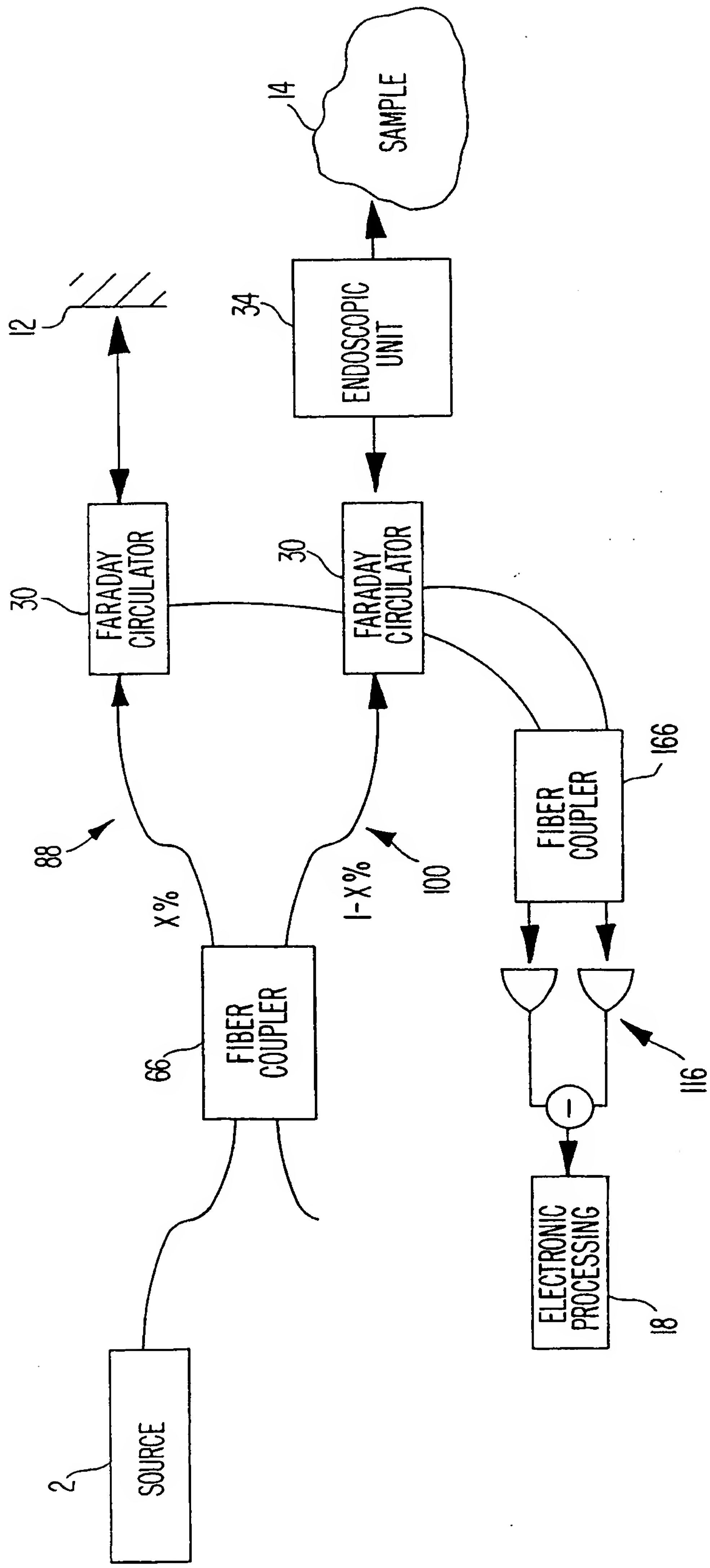


FIG. 1

SUBSTITUTE SHEET (RULE 26)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12
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30
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100
FIBER COUPLER
66
116
SOURCE
2
ELECTRONIC PROCESSING
18

FIG. 3

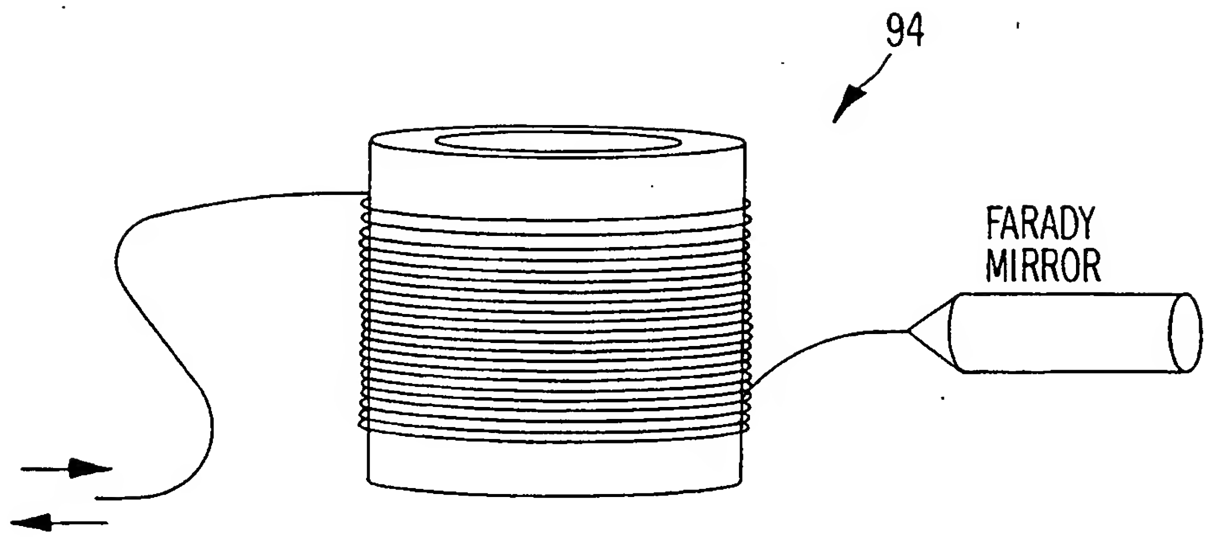


FIG. 5A

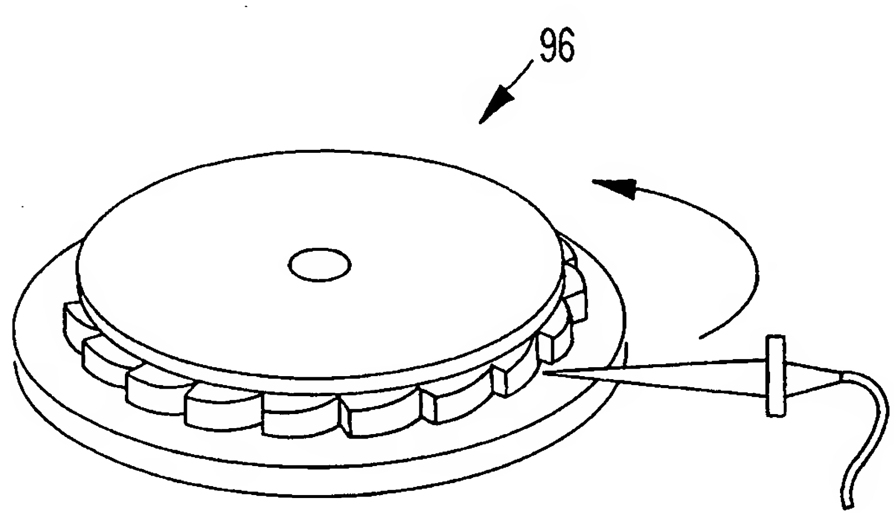


FIG. 5B

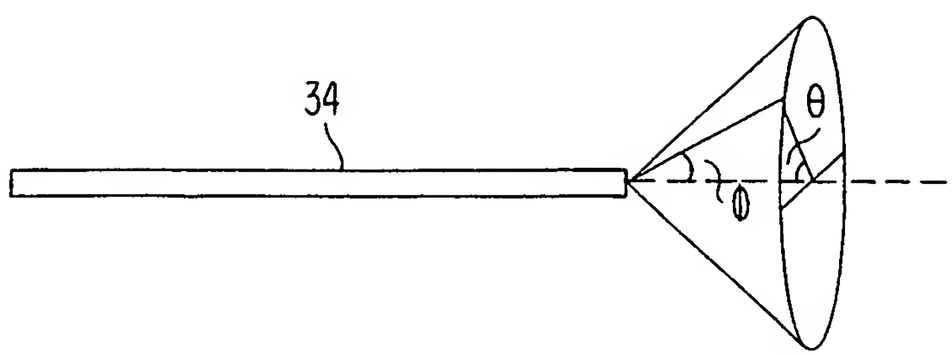


FIG. 7A

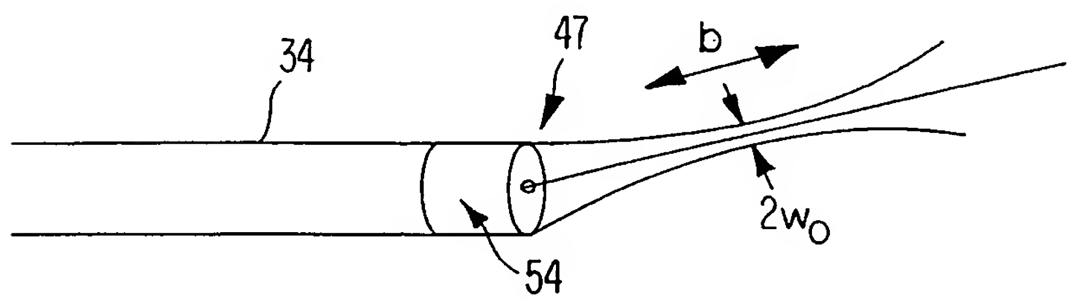


FIG. 7B

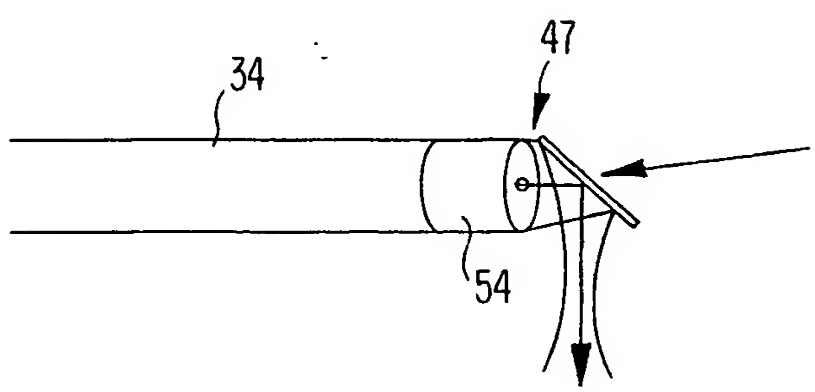
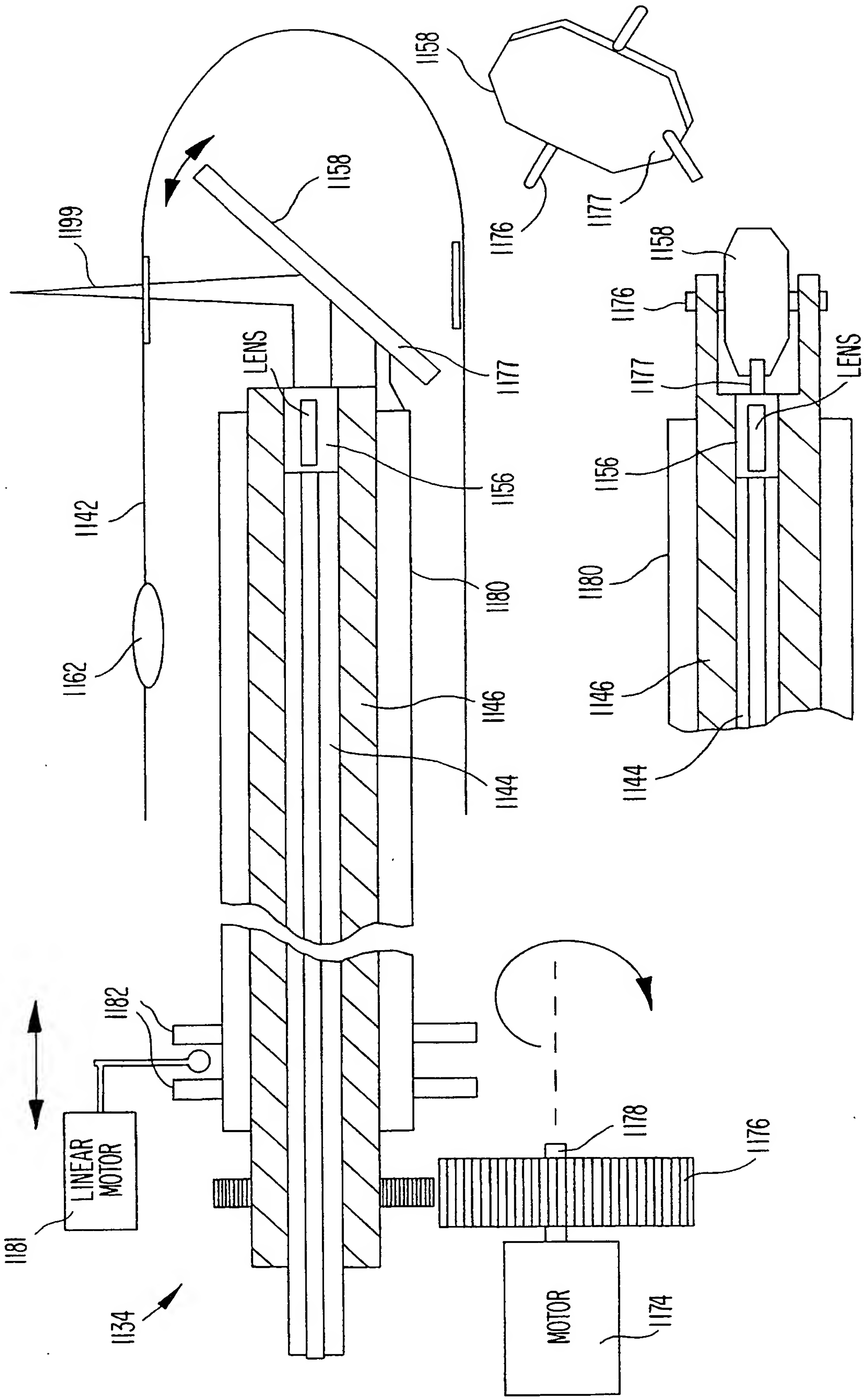


FIG. 7C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1181
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1178
MOTOR
1174

FIG. 9

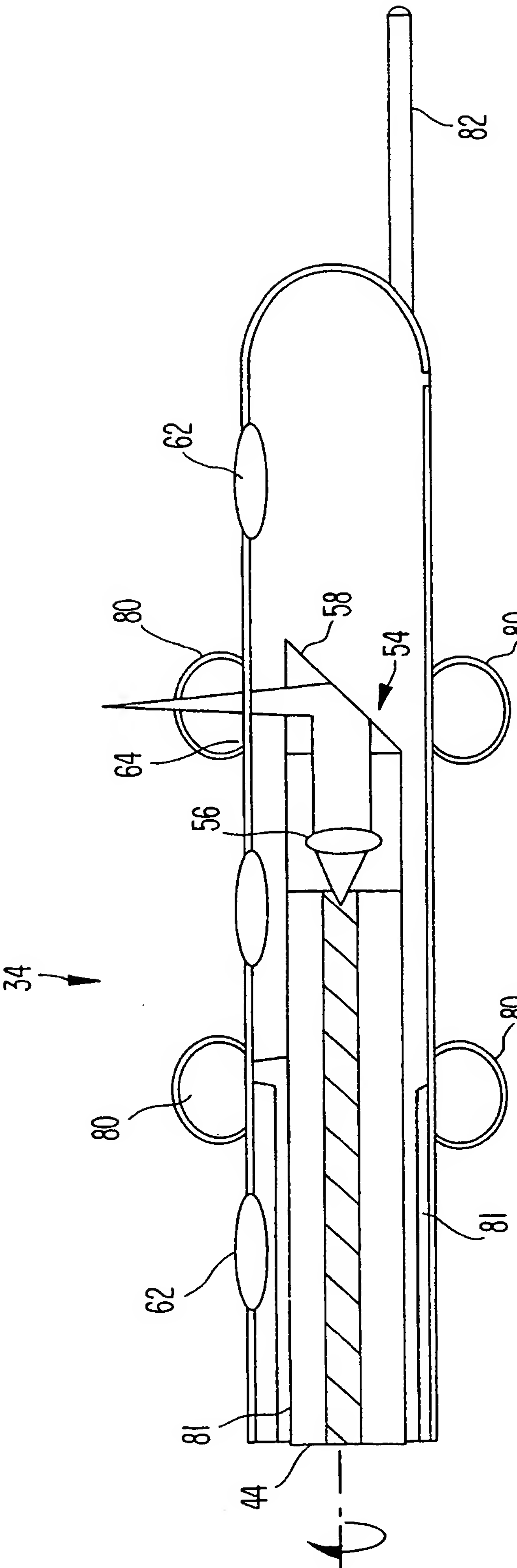


FIG. 11A

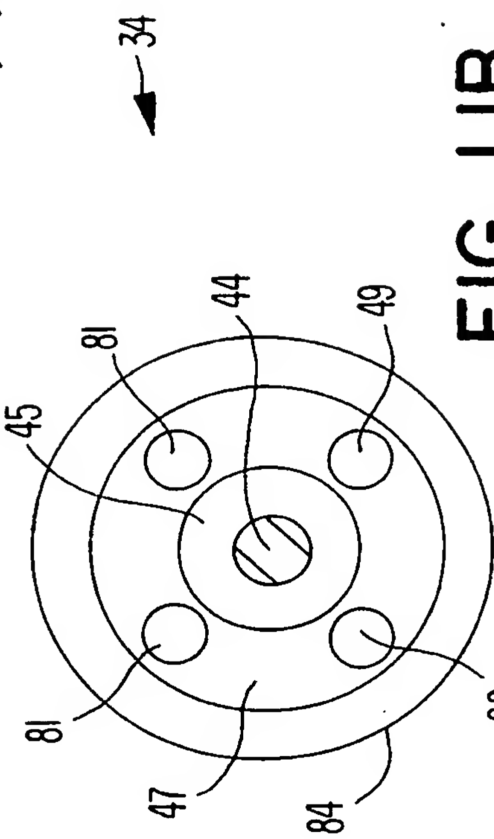


FIG. 11B

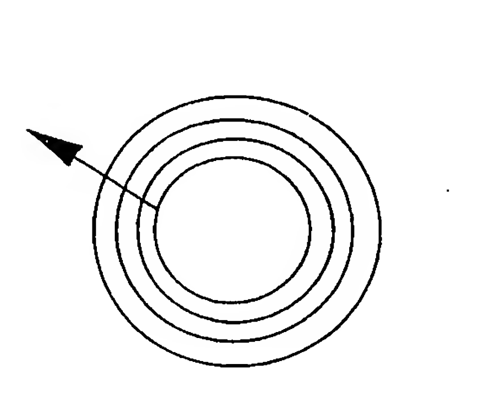


FIG. 13A

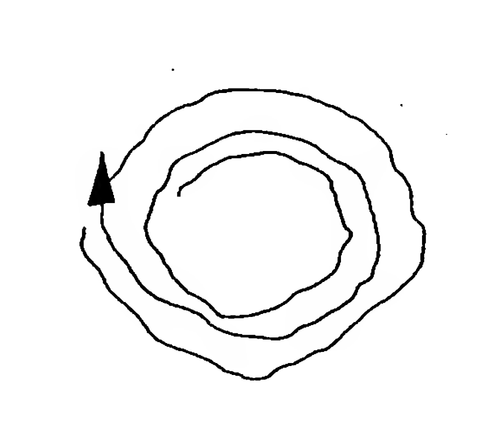


FIG. 13B

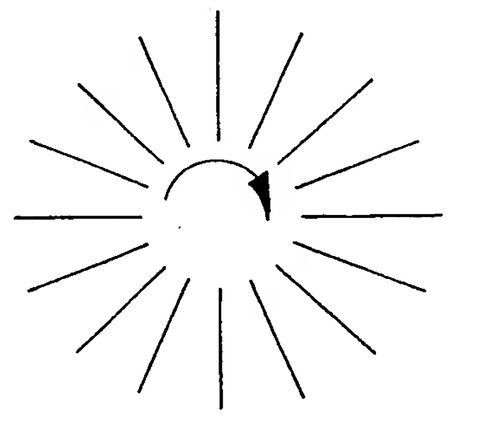


FIG. 13C

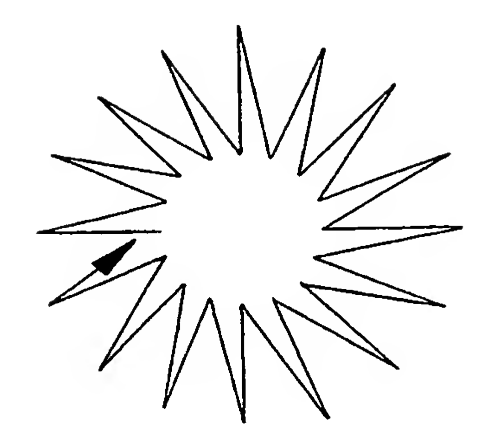
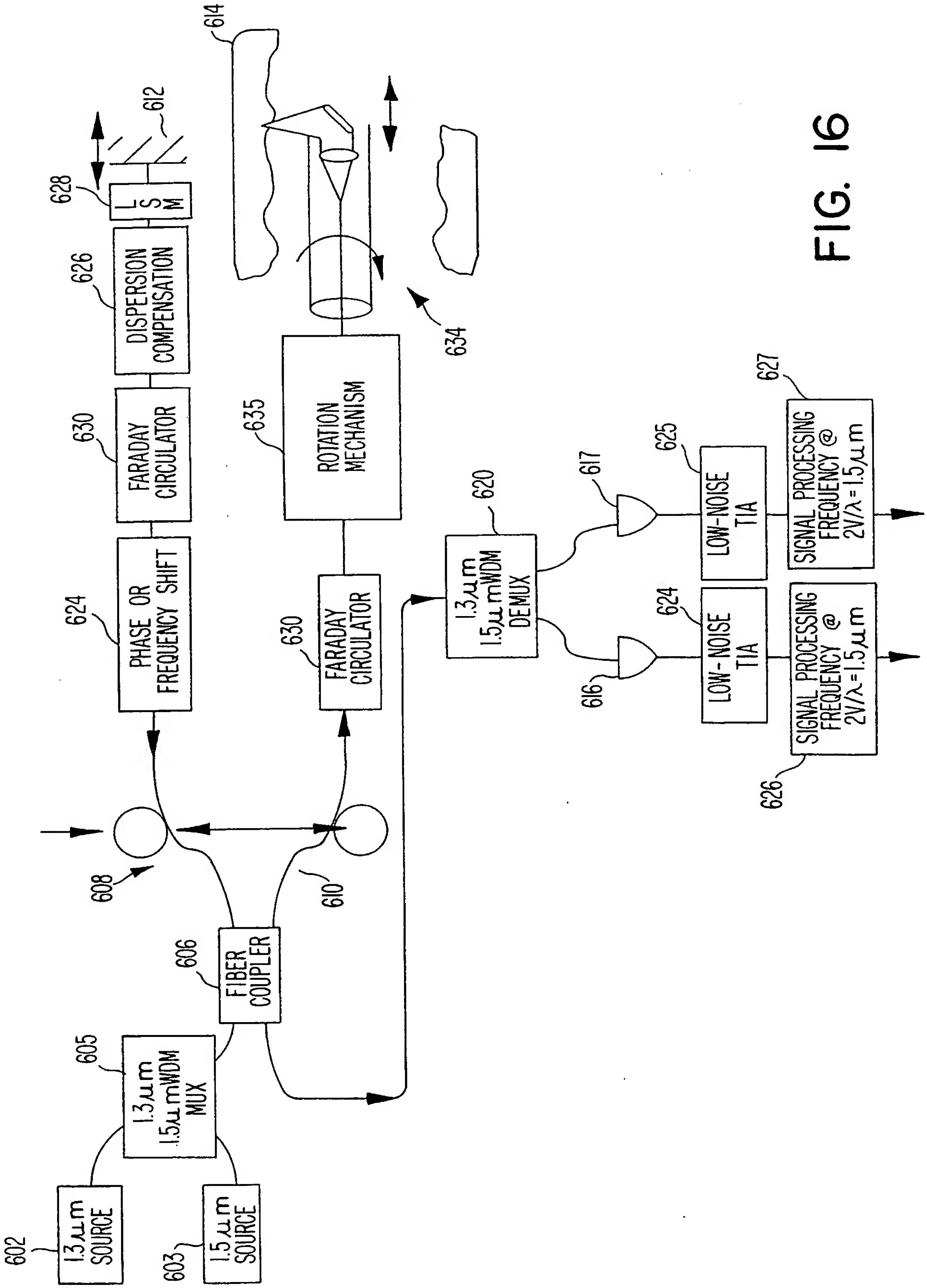


FIG. 13D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626
DISPERSION
COMPENSATION
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FARADAY
CIRCULATOR
624
PHASE OR
FREQUENCY SHIFT
635
ROTATION
MECHANISM
634
630
FARADAY
CIRCULATOR
620
1.3μm
1.5μ mWDM
DEMUX
617
625
LOW-NOISE
TIA
627
SIGNAL PROCESSING
FREQUENCY @
2V/λ=1.5μm
616
624
LOW-NOISE
TIA
SIGNAL PROCESSING
FREQUENCY @
2V/λ=1.5μm
626
608
610
606
FIBER
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MUX
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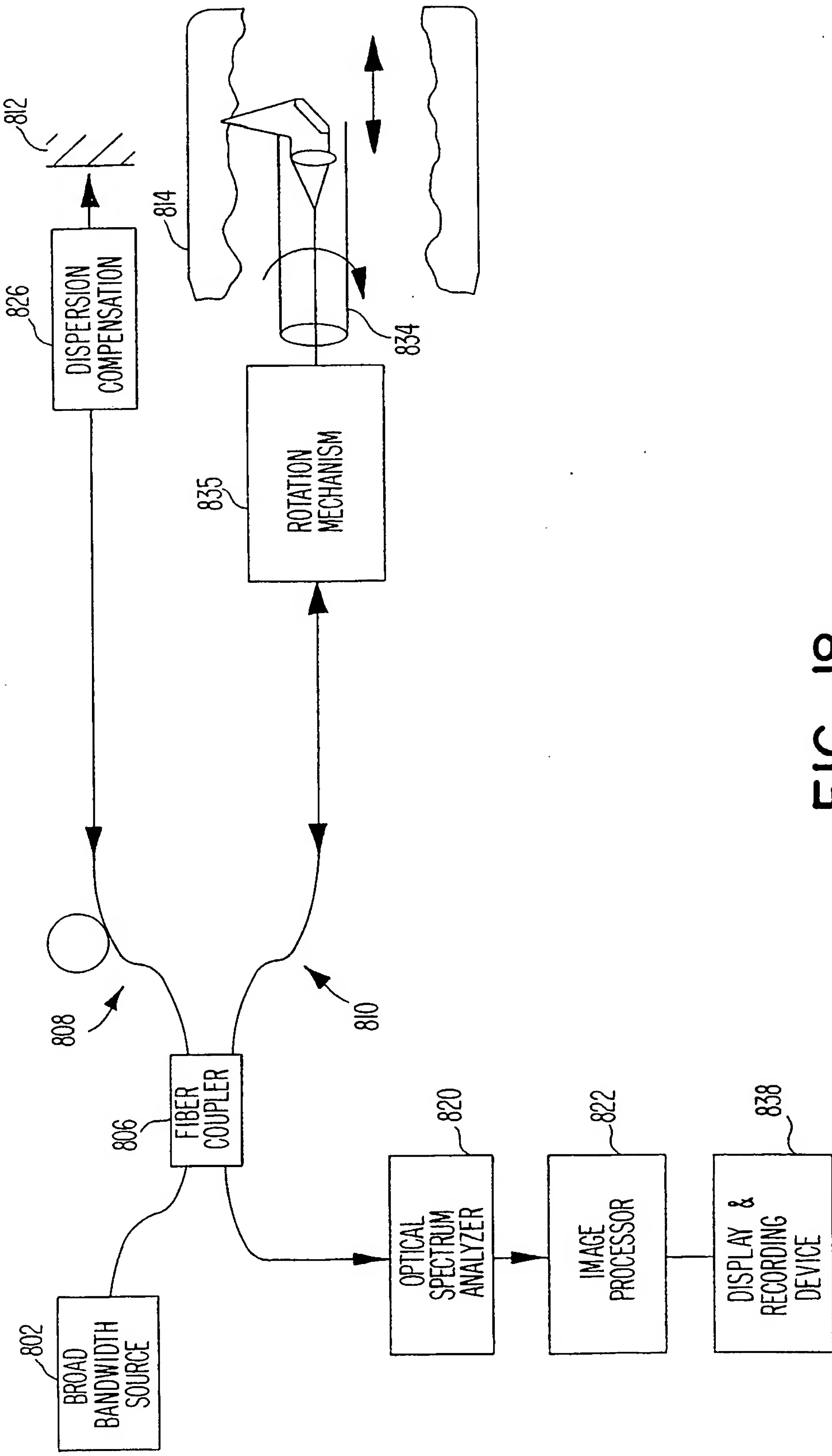
SOURCE
603
1.5μm
SOURCE

FIG. 16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826
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834
835
ROTATION MECHANISM
808
810
806
FIBER COUPLER
820
822
838
802
BROAD BANDWIDTH SOURCE
OPTICAL SPECTRUM ANALYZER
IMAGE PROCESSOR
DISPLAY & RECORDING DEVICE

FIG. 18

INTERNATIONAL SEARCH REPORT

Inte al Application No
PCT/US 97/03033

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G01B11/12 G01B9/02 G01B11/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G01B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 325 177 A (PETERSON LAUREN M) 28 June 1994 see column 4, line 4 - column 5, line 47; figures ---	1-3
A	JP 04 135 552 A (OLYMPUS OPTICAL CO LTD) 11 May 1992 see the whole document ---	1,15
A	JP 60 235 005 A (SUMITOMO KINZOKU KOGYO KK) 21 November 1985 see the whole document ---	1,2,17
A	US 5 459 570 A (SWANSON ERIC A ET AL) 17 October 1995 cited in the application see the whole document --- -/--	1

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
3 June 1997	20.06.97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Ramboer, P

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Intu al Application No
PCT/US 97/03033

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